UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

In re:	)	
	)	Case No. 1:12-md-2343
Skelaxin (Metaxalone) Antitrust Litigation	)	
	)	Judge Curtis L. Collier
	)	

MEMORANDUM

Pharmaceutical antitrust litigation presents unique challenges due in part to the Constitutional and statutory protection afforded intellectual property rights and the peculiar regulatory scheme that governs pharmaceutical approval, sales, and marketing. Those unique challenges come into play in all aspects of the litigation even in the early stages. One such challenge presented in the early stages of litigation is whether the claims brought by an antitrust plaintiff sufficiently allege facts that survive a Fed. R. Civ. P. 12(b)(6) motion.

The Court is faced with such a motion in this case filed by Defendants King Pharmaceuticals LLC, formerly known as King Pharmaceuticals, Inc. ("King") and Mutual Pharmaceutical Company, Inc. ("Mutual") (collectively, "Defendants") (Court File No. 84).

Bound by the relevant and applicable law concerning dismissing a claim for failure to state a plausible claim for relief, and after giving careful consideration to the parties' substantive and substantial written submissions, and the parties' arguments at the April 16 extensive oral argument hearing, the Court concludes that it must **DENY** Defendants' motion to dismiss (Court File No. 84).

I. THE PARTIES

The Plaintiffs in this case are a collection of large businesses, pharmacies, labor

organizations, health insurance companies and entities, and individuals that purchased or reimbursed purchasers for buying metaxalone, a prescription muscle relaxant sold under the brand name Skelaxin. Skelaxin is manufactured and sold by King. Many of the Plaintiffs have chosen to proceed by way of a class action lawsuit. The Court has divided the putative Class Plaintiffs into three groups: the Direct Purchasers ("Direct Purchaser Plaintiffs" or "Direct Purchasers"), the Indirect Purchasers for Resale ("Indirect Purchaser Plaintiffs" or "Indirect Purchasers"), and the End Payors ("End Payor Plaintiffs" or "End Payors") (collectively, "Plaintiffs" or "Class Plaintiffs").[1,2] The Direct Purchaser class is comprised primarily of wholesalers who allege they purchased Skelaxin directly from King during the class period (Court File No. 65 ("DPP Compl."), ¶¶ 13-18). The named plaintiffs in this class include Professional Drug Company, Inc.; Meijer, Inc. and Meijer Distribution, Inc.; Rochester Drug Co-Operative, Inc.; Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors and Stephen L. LaFrance Holdings, Inc.; and Ahold USA, Inc. The Indirect Purchaser for Resale class is made up primarily of retail pharmacies who allege they indirectly purchased Skelaxin for resale during the class period (Court File No. 64 ("IPP Compl."), ¶¶ 12-15). The named plaintiffs in this class are Johnson's Village Pharmacy, Inc.; Russell's Mr. Discount

[1] The Court has not certified the putative classes in this case yet. Class certification litigation has just recently begun.

[2] In addition to the three proposed Plaintiffs' classes, three additional Plaintiffs' groups are involved in the case but have indicated that if a class that includes them is certified they will opt out of that class. Treating this as a preemptive opt-out, the Court has not included them in any of the litigation regarding the putative classes, and the instant memorandum and order will not apply to these groups.

The Direct Purchaser Individual Plaintiffs are the *Walgreen* Plaintiffs (Case No. 1:12-cv-203) and the *Rite Aid* Plaintiffs (Case No. 1:13-cv-5). The End Payor Individual Plaintiffs are the *Blue Cross Blue Shield* Plaintiffs (2:12-cv-464).

Drugs, Inc.; Knight Pharmacy, Inc.; and Bidwell Pharmacy & Medical Supply, Inc. Finally, the End Payor class is comprised of primarily health and welfare benefit funds, trust funds, and insurance companies who allege they purchased and/or provided reimbursement for Skelaxin or its generic equivalent in various states (Court File No. 67 ("EPP Compl."), ¶¶ 8-13). The named plaintiffs in this class are United Food and Commercial Workers Union and Midwest Health Benefits Fund; Pirelli Armstrong Retiree Medical Benefits Trust; Allied Services Division Welfare Fund; Plumbers and Pipefitters Local 572 Health and Welfare Fund; Laborers Trust Fund for Northern California; and Louisiana Health Service Indemnity Company.

The Defendants in this case are King Pharmaceuticals, LLC and Mutual Pharmaceutical Company, Inc. King is a pharmaceutical company with its principal place of business in this district in Bristol, Tennessee. King manufactures and sells Skelaxin. Mutual is also a pharmaceutical company that develops, manufactures, and sells drugs. It has its principal place of business in Philadelphia, Pennsylvania.

II. PROCEDURAL HISTORY

In January 2012 the first lawsuit in this matter was filed against Defendants in the Eastern District of Tennessee. Since that time several more cases have been filed in various jurisdictions. The Judicial Panel on Multidistrict Litigation transferred all of the pending actions to the Court in a transfer order issued on April 17, 2012. The Court consolidated all of the actions into this Multidistrict Litigation ("MDL") and subdivided the action into the three classes.

On November 2, 2012, all of the Class Plaintiffs--that is, the Direct Purchasers, Indirect Purchasers, and End Payors--filed amended consolidated class action complaints. On January 4,

2013, Defendants filed the pending motion to dismiss. The Class Plaintiffs filed a consolidated response in opposition to Defendants' motion to dismiss (Court File No. 102), and Defendants submitted a reply (Court File No. 132). The Court held extensive oral arguments on April 16, 2013, at which time counsel for Defendants and counsel for the three proposed Plaintiffs' classes presented their arguments in support of their positions on behalf of their respective parties**.** Counsel were very well prepared and did an exemplary job in their arguments. They demonstrated a complete command of the facts, mastery of the applicable law, and an in-depth understanding of the underlying policy reasons and considerations of patent and antitrust law. The Court found their arguments enlightening and of great assistance to the Court in resolving this motion.

III. *TWOMBLY* & *IQBAL*

In 2007 the Supreme Court changed the framework for considering a Rule 12(b)(6) motion in antitrust cases. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). While retaining much of the familiar framework of the 12(b)(6) analysis *Twombly* added a plausibility requirement. The pre-*Twombly* analysis started with the proposition that a Rule 12(b)(6) motion should be granted when it appears "beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Lewis v. ACB Bus. Servs., Inc.*, 135 F.3d 389, 405 (6th Cir. 1998). For purposes of this determination, the Court construes the complaint in the light most favorable to the plaintiff and assumes the veracity of all well-pleaded factual allegations in the complaint. *Thurman v. Pfizer, Inc.*, 484 F.3d 855, 859 (6th Cir. 2007). The same deference does not extend to bare assertions of legal conclusions, however, and the court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986). The Court

next considers whether the factual allegations, if true, would support a claim entitling the plaintiff to relief. *Thurman*, 484 F.3d at 859.

In *Twombly* the Court considered a class action complaint brought under § 1 of the Sherman Act. The complaint in that case, according to the Court, alleged that major telecommunications companies engaged in certain parallel conduct unfavorable to competitive telecommunications companies. *Id.* at 548-49. The complaint failed to contain factual content suggesting an agreement, "as distinct from identical, independent action." *Id.* at 549. The Court held that it was not requiring "heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face." *Id.* at 570. The Court began its analysis by observing that because "the Sherman Act 'does not prohibit [all] unreasonable restraints of trade . . . but only restraints effected by a contract, combination, or conspiracy,'" "'[t]he crucial question' is whether the challenged anticompetitive conduct 'stem[s] from independent decision or from an agreement, tacit or express.'" *Id.* at 553 (citations omitted). The Court then repeated the familiar formulation of the requirements necessary to survive a 12(b)(6) motion. After stating those the Court said:

> In applying these general standards to a § 1 claim, we hold that stating such a claim requires a complaint with enough factual matter (taken as true) to suggest that an agreement was made. Asking for plausible grounds to infer an agreement does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal agreement. And, of course, a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and "that a recovery is very remote and unlikely."

Id. at 556 (footnote omitted).

The Court explained that the requirement of plausibility adheres to the requirement of Fed. R. Civ. P. 8(a)(2).

> The need at the pleading stage for allegations plausibly suggesting (not merely

> consistent with) agreement reflects the threshold requirement of Rule 8(a)(2) that the "plain statement" possess enough heft to "sho[w] that the pleader is entitled to relief." A statement of parallel conduct, even conduct consciously undertaken, needs some setting suggesting the agreement necessary to make out a § 1 claim; without that further circumstance pointing toward a meeting of the minds, an account of a defendant's commercial efforts stays in neutral territory. An allegation of parallel conduct is thus much like a naked assertion of conspiracy in a § 1 complaint: it gets the complaint close to stating a claim, but without some further factual enhancement it stops short of the line between possibility and plausibility of "entitle[ment] to relief."

Twombly, 550 U.S. at 557.

The Court expressed the practical concern that allowing claims that possess only a mere possibility of loss causation would permit a claimant with "a largely groundless claim" to "take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value." *Id.* at 557-58 (citations omitted). The Court recognized that antitrust discovery and litigation can be very expensive. *Id.* at 558.

From *Twombly* we learn that a complaint in an antitrust case alleging conspiracy must contain sufficient facts, taken as true, that suggest an illegal agreement was made. The complaint must include sufficient factual allegations that are plausible on its face. The complaint must contain factual allegations of "some setting," "circumstance pointing toward a meeting of the minds," an "independent allegation of actual agreement." And the Court pointed out that even if the judge concludes it is unlikely that plaintiff can prove the alleged facts and that a recovery is remote and unlikely, the judge must still reject the motion to dismiss if the complaint is well pleaded. *Twombly*, 550 U.S. at 556.

In *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), the Court built upon its decision in *Twombly* and clarified that it was not limited to just antitrust actions. *Id.* at 684. The Court acknowledged that although a complaint need only contain a "short and plain statement of the claim showing that the

pleader is entitled to relief," *id. at* 677-78 (quoting Fed. R. Civ. P. 8(a)(2)), this statement must nevertheless contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678. "[T]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id*. (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Plausibility as explained by the Court "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting Fed. R. Civ. P. 8(a)(2)).

The Court also explained that it recognized that determining whether a complaint states a plausible claim for relief is not a matter of mathematics but rather is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.*

Armed with the teachings from *Twombly* and *Iqbal*, the Court will endeavor to apply those teachings and with its "judicial experience and common sense" address Defendants' motion to dismiss.

IV. BACKGROUND

A. Regulatory and Statutory Framework

The regulatory and statutory framework in which cases of this type arise has been fully explained in many cases. The Court will merely summarize that framework here. The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. §§ 301 *et seq.*, sets forth the guidelines

for the Food and Drug Administration ("FDA") drug approval process. In 1984, Congress passed the Hatch-Waxman Amendments to the Act, which instituted new rules for generic drug approval. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Amendments were passed after Congress determined the Act's "cumbersome drug approval process delayed the entry of relatively inexpensive generic drugs into the market place." *In re Cardizem CD Antitrust Litig. ("In re Cardizem I")*, 105 F. Supp. 2d 618, 627-28 (E.D. Mich. 2000) (quoting *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000)).

Under the Hatch-Waxman Amendments, a potential generic manufacturer of a patented "pioneer" or brand name drug can file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j)(1); *In re Cardizem CD Antitrust Litig. ("In re Cardizem II")*, 332 F.3d 896, 901 (6th Cir. 2003). "Instead of submitting new safety and efficacy studies, an ANDA may rely on the FDA's prior determination, made in the course of approving an earlier 'pioneer' drug, that the active ingredients of the proposed new drug are safe and effective." *In re Cardizem II*, 332 F.3d at 901 (citing 21 U.S.C. § 355(j)(2)(A)). The ANDA applicant must also make one of four certifications that the "proposed generic drug does not infringe any patent listed with the FDA as covering the pioneer drug." *Id.* (quoting § 355(j)(2)(A)(vii)).

One certification at issue in this case is the "paragraph IV certification," which allows the ANDA applicant to certify the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). Under a paragraph IV certification, the ANDA applicant must give notice to the patent holder. *Id.* (citing 21 U.S.C. § 355(j)(2)(B)). The patent holder has the option of

bringing a patent-infringement suit against the ANDA applicant within forty-five days of receiving notice. *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iii)). If a lawsuit is filed, "a thirty-month stay goes into effect, meaning that unless before that time the court hearing the patent infringement case finds that the patent is invalid or not infringed, the FDA cannot approve the generic drug before the expiration of that thirty-month period." *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iii)(I)). "In order to encourage generic entry, and to compensate for the thirty-month protective period accorded the patent holder, the first generic manufacturer to submit an ANDA with a paragraph IV certification receives a 180–day period of exclusive marketing rights, during which time the FDA will not approve subsequent ANDA applications." *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iv)).

With respect to labeling, the FDCA generally requires that the ANDA contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a [listed or brand name drug]," 21 U.S.C. § 355(j)(2)(A)(i), and " information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v). If the ANDA applicant is seeking approval of a condition of use (or "method of use") that is not a patented method of use associated with the brand name or listed drug in the Orange Book,[3] the applicant "must submit a section viii statement declaring that the patent does not claim such a use." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1046 (Fed. Cir. 2010) (citing 21 U.S.C. § 355(j)(2)(A)(viii)). The ANDA applicant is also required to "remove or 'carve out' any mention of the patented method of use from

[3] The *Approved Drug Products with Therapeutic Equivalence Evaluations* list, also known as the "Orange Book," is a source where the FDA publishes both the names of drugs that have been approved and their related patents. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045 (Fed. Cir. 2010).

the proposed label for the generic drug." *Id.* (citing 21 C.F.R. § 314.92(a)(1) and *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359, 1361 (Fed. Cir. 2010)). Unlike the process for filing a paragraph IV certification, submitting a section viii statement "will not by itself delay approval of an ANDA." *Id.*

Finally, several of Plaintiffs' allegations pertain to the filing of FDA "citizen petitions." A citizen petition, which can be filed by private entities, may request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.30; *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 303 (E.D. Pa. 2011). In 2007, 21 U.S.C. § 355 was amended so that the FDA could approve an ANDA even if a citizen petition was pending "unless the FDA determines that it is 'necessary to protect the public health' to resolve the petition before approving an ANDA." *Id.* (citing 21 U.S.C. § 355(q)(1)(A)(ii) and Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified in various sections of titles 21, 42 of the U.S. Code)).

B. Relevant Facts

The Court is stating these facts as they are alleged in the complaints. The Court states them in the light most favorable to Plaintiffs. In stating the facts in this manner the Court is not offering an opinion that it thinks Plaintiffs can prove these facts or are likely to recover. As the Supreme Court stated in *Twombly*, "a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" 550 U.S. at 556. At this stage of the case the Court is merely called upon to determine whether Plaintiffs' allegations are "plausible."

In 1962, the FDA approved the sale and marketing of metaxalone in the form of a 400 mg

pill taken in 800 mg increments (DPP Compl. ¶¶ 69-76; IPP Compl. ¶¶ 67-74; EPP Compl. ¶¶ 64-71). The drug was designed to provide relief to individuals suffering from acute musculoskeletal conditions. The drug was sold and marketed under the brand name Skelaxin. The patent on the active ingredient metaxalone (patent number 3,062,827 or the "'827 patent"), which was issued by the Patent and Trademark Office ("PTO") in 1962, expired in or around 1979. Although the label did not indicate whether Skelaxin was to be taken with or without food, Plaintiffs allege the public literature about the product indicated the drug should be taken with food.

The pharmaceutical company Elan sold and marketed Skelaxin between the years of 1998 and 2003. Elan took various steps to delay the entry of generic metaxalone in the market (DPP Compl. ¶¶ 77-110; IPP Compl. ¶¶ 75-108; EPP Compl. ¶¶ 72-104). Among other acts, Elan sought a patent for the results of a "food effects" study commissioned in 2001. Elan believed the study showed participants who took metaxalone with food had a statistically significant higher rate and extent of absorption of the drug than those who did not eat when taking metaxalone. In June 2002, the PTO issued patent number 6,407,128 (the "'128 patent") with respect to the findings of Elan's food effects study.

As early as 2001, various manufacturers began to seek approval of their generic metaxalone products (DPP Compl. ¶¶ 92, 103; IPP Compl. ¶¶ 90, 101; EPP Compl. ¶¶ 86, 97). Eon, a generic manufacturer, was the first to file its ANDA application for a 400 mg metaxalone product followed by another manufacturer in 2002 named CorePharma. In light of the '128 patent issued mid-2002, Eon filed a paragraph IV certification and sent notice to Elan (DPP Compl. ¶¶ 111-18; IPP Compl. ¶¶ 109-16; EPP Compl. ¶¶ 105-12). In the certification, Eon alleged its 400 mg generic metaxalone product would not infringe the '128 patent and that the '128 patent was invalid. On January 2, 2003,

Elan filed a patent infringement lawsuit against Eon, which Plaintiffs allege was a sham. Soon thereafter, generic manufacturer CorePharma also filed a paragraph IV certification and sent notice to Elan.[4] Elan filed a patent infringement suit against CorePharma on March 7, 2003. Around March 2003, a third generic manufacturer, Defendant Mutual, filed an ANDA application for a 400 mg generic metaxalone product. In contrast to Eon and CorePharma, Mutual did not file a paragraph IV certification. Instead, it filed a certification under "section viii" seeking only to carve out any infringing "method of use" information on the label in light of the '128 patent.

In June 2003, King acquired the rights to Skelaxin and another drug from Elan, as well as the license rights to the '128 patent and the patent application for what would become the '102 patent (DPP Compl. ¶¶ 123-36; IPP Compl. ¶¶ 121-134; EPP Compl. ¶¶ 117-30). Patent number 6,683,102 (the "'102 patent") was issued in January 2004 and was "directed to methods of providing metaxalone to patients while informing them that taking metaxalone with food results in higher blood levels of metaxalone" (DPP Compl. ¶¶ 129-30; IPP Compl. ¶¶ 127-28; EPP Compl. ¶¶ 123-24). King subsequently listed the patent in the Orange Book (DPP Compl. ¶¶ 131-36; IPP Compl. ¶¶ 129-34; EPP Compl. ¶¶ 125-30). Plaintiffs allege the patent was invalid because, among other reasons, the benefits of taking metaxalone with food were well known. Thus, Plaintiffs allege King's findings were invalid for "anticipation by the prior art" and "obviousness." Plaintiffs allege King knew the patent was invalid when it listed it in the Orange Book.

On January 29, 2004, Mutual notified King that it had filed a paragraph IV certification with respect to the '102 patent (DPP Compl. ¶ 137; IPP Compl. ¶ 135; EPP Compl. ¶ 131). Mutual noted

[4] That following month, CorePharma petitioned the FDA to waive the paragraph IV certification requirement so it could file a section viii certification instead.

in its letter to King that "[the] institution of baseless litigation against an applicant seeking approval to market a generic drug product can give rise to antitrust liability. The Federal Trade Commission . . . has strongly condemned such tactics. . . . Suffice it to say, should King [or its subsidiary] choose the precarious route of filing suit against Mutual, it is reasonably certain that the FTC will have a great interest in such litigation" (*id.*). King subsequently filed an infringement suit against Mutual on March 12, 2004 as to the '102 patent, which Plaintiffs allege was a sham (DPP Compl. ¶¶ 139-40; IPP Compl. ¶¶ 137-38; EPP Compl. ¶¶ 133-34).

In 2004, the FDA determined the "food effects" data that was the subject of the '128 patent could, in fact, be carved out from the metaxalone label (DPP Compl. ¶¶ 141-45; IPP Compl. ¶¶139-43; EPP Compl. ¶¶ 135-39). The FDA concluded the information protected by the '128 patent could be carved out because metaxalone had been marketed for years without this information and there had been few adverse reports. Hence, generic manufacturers of metaxalone could proceed with certification under section viii, which was less likely to result in delay than a paragraph IV certification. King filed two petitions with the FDA in March 2004, however, seeking reconsideration of the decision to allow generic manufacturers to carve the food effects data out of their labels (DPP Compl. ¶¶ 147-54; IPP Compl.¶¶ 145-52; EPP Compl. ¶¶ 141-48). In the second petition, King also requested that the FDA stay the approval of any generic metaxalone products until the FDA had ruled on King's petitions. Plaintiffs allege these petitions were baseless because no reasonable petitioner would have thought they could have succeeded on the merits based on the arguments raised in King's petitions. Mutual and CorePharma filed documents with the FDA between April 2004 and late 2005 opposing King's petitions (DPP Compl. ¶¶ 155-65; IPP Compl. ¶¶ 153-63; EPP Compl. ¶¶ 149-59).

In 2004, Eon sought to amend its ANDA in order to obtain approval of an 800 mg generic metaxalone (DPP Compl. ¶¶ 166-70; IPP Compl. ¶¶ 164-68; EPP Compl. ¶¶ 160-64).[5] Eon filed a paragraph IV certification for its 800 mg product with respect to both the '102 and '128 patents. King subsequently brought a patent infringement suit against Eon. This case was consolidated with the earlier patent infringement suit King had filed against Eon with respect to the 400 mg generic metaxalone.

Beginning in fall 2005, Defendants began to lay the groundwork for the alleged conspiracy (DPP Compl. ¶¶ 171-80; IPP Compl. ¶¶ 169-78; EPP Compl. ¶¶ 165-74). Mutual sponsored three metabolism studies in 2005 to learn about various aspects of metaxalone. Then, in October 2005, Dr. Markison, King's President and Chief Executive Officer, Adriane Sax, King's Vice President of Business Development, and Dr. Spireas, head of Mutual's research and development activities for metaxalone[6] held a meeting at which Markison disclosed King's efforts to settle the patent infringement cases involving Skelaxin. In particular, Markison indicated King "would make substantial annual payments to those generic manufacturers to settle the patent litigations that were threatening King's monopoly" (DPP Compl. ¶ 175; IPP Compl. ¶ 173; EPP Compl. ¶ 169).

On December 6, 2005, according to Plaintiffs, King and Mutual entered into an agreement (the "agreement" or the "King-Mutual" agreement) under which Mutual agreed "(i) not to enter the market with any generic metaxalone product, but instead (ii) to aid King in its effort to delay and obstruct other would-be generic competitors from gaining FDA approval and launching competitive

[5] King had recently received approval for an 800 mg product.

[6] At the time, Dr. Spireas was also serving as president of SigmaPharm, a company that developed pharmaceutical products and technology.

generic products" (DPP Compl. ¶ 176; IPP Compl. ¶ 174; EPP Compl. ¶ 170). Plaintiffs allege King "bought" Mutual's allegiance by agreeing to pay Mutual $35 million plus at least 10% of the revenue from Skelaxin sales (DPP Compl. ¶ 178; IPP Compl. ¶ 176; EPP Compl. ¶ 172). Plaintiffs claim King has paid Mutual in excess of $200 million. Plaintiffs allege the agreement caused Mutual to cease any efforts to launch a generic metaxalone product and instead assist King in delaying the entry of other generic competitors (DPP Compl. ¶ 180; IPP Compl. ¶ 178; EPP Compl. ¶ 174).

Two days after entering into the agreement, Mutual withdrew its opposition to King's FDA petitions (DPP Compl. ¶¶ 181-85; IPP Compl. ¶¶ 179-83; EPP Compl. ¶¶ 175-79). Mutual and King then collaborated to obtain a patent for Mutual's metaxalone metabolism data (DPP Compl. ¶¶ 186-91; IPP Compl. ¶¶ 184-89; EPP Compl. ¶¶ 180-85). The PTO issued patent number 7,122,566 (the "'566 patent") to Mutual, which Mutual then licensed to King and King listed in the Orange Book. As with the other patents, Plaintiffs allege the patent was invalid.

Plaintiffs also contend Defendants falsely maintained the '102 patent litigation case involving King and Mutual (DPP Compl. ¶¶ 192-202; IPP Compl. ¶¶ 190-200; EPP Compl. ¶¶ 186-96). Plaintiffs allege King and Mutual did not inform the court about their "agreement." On the contrary, on May 15, 2006, King and Mutual filed a stipulation under seal requesting that the court stay the case until the FDA issued its decision on King's 2004 petitions. Plaintiffs allege "[w]hile the Mutual '102 patent litigation had been a sham from the outset (as it had no likelihood of success), with Mutual's complicity in it, the case was now a concerted fraud on the court. Although there was no longer any justiciable controversy, both parties continued the litigation for an additional five years as a subterfuge to maintain their outward appearances--to the FDA, the FTC, and the public--as adversaries rather than conspirators" (DPP Compl. ¶ 200; *see* IPP Compl. ¶ 198;

EPP Compl. ¶ 194).

In December 2005, CorePharma followed Eon's lead and amended its ANDA to seek approval for an 800 mg tablet (DPP Compl. ¶¶ 203, 216-17; IPP Compl. ¶¶ 201, 214-15; EPP Compl. ¶¶ 197, 210-11). King did not file suit in this instance. Rather, on May 11, 2006, King and CorePharma entered into a Manufacturing and Supply Agreement such that CorePharma became King's "authorized distributor" and agreed to manufacture and supply the 800 mg tablet to King. The previous suit King had filed against CorePharma with respect to its 400 mg tablet would continue until January 2, 2008, when King and CorePharma would enter into a settlement agreement. The settlement agreement provided that CorePharma could enter the market with an "authorized generic" the earlier of December 1, 2012, or the date of the first sale of generic metaxalone by a competitor.

Between February 2007 and January 2008, King and Mutual filed more baseless or sham petitions with the FDA (DPP Compl. ¶¶ 206-15; IPP Compl. ¶¶ 204-13; EPP Compl. ¶¶ 200-09). In July 2008, the FDA denied the petitions (DPP Compl. ¶¶ 218-21; IPP Compl. ¶¶ 216-19; EPP Compl. ¶¶ 212-15). Plaintiffs allege this result was "obvious and predictable from the face of the petitions: neither even purported to present any clinically meaningful data" (*id.*).

On November 5, 2008, Sandoz (formerly "Eon") filed an amended ANDA for its 800 mg generic metaxalone with a paragraph IV certification alleging the '566 patent was invalid or would not be infringed (DPP Compl. ¶¶ 222-24; IPP Compl. ¶¶ 220-22; EPP Compl. ¶¶ 216-18). On December 5, 2008, Defendants brought a patent infringement suit against Sandoz with respect to the '566 patent. Plaintiffs allege the suit was baseless and no reasonable litigant would have thought it could have prevailed on the merits.

As Defendants continued to further their anticompetitive scheme, several significant events took place. With respect to the '128 and '102 patent infringement cases involving King and Sandoz (formerly Eon's cases), a district court judge granted summary judgment in Sandoz's favor finding the patents were invalid (DPP Compl. ¶¶ 225-29; IPP Compl. ¶¶ 223-27; EPP Compl. ¶¶ 219-23).[7] In light of that decision, on March 30, 2010, the FDA approved Sandoz's ANDA for the marketing and sale of an 800 mg generic metaxalone--the first generic form of metaxalone that would enter the market (DPP Compl. ¶¶ 234-40; IPP Compl. ¶¶ 232-38; EPP Compl. ¶¶ 228-34). As Sandoz was preparing for an immediate launch, Defendants sought to delay the launch by filing a motion for a preliminary injunction in the '566 patent litigation case on April 1, 2010. Sandoz was temporarily restrained from releasing its generic metaxalone product in the market. On April 6, 2010, the court modified the order and set a date for a hearing, but noted the order would be dissolved in the event CorePharma launched its competing generic drug. CorePharma did, in fact, launch its generic metaxalone drug pursuant to the terms of the 2008 settlement agreement it had entered into with King. Therefore, the court vacated the temporary restraining order on April 9, 2010, and Sandoz entered the market that same day. Although Sandoz had launched its product, the '566 case still proceeded to trial.

On April 19, 2010, SigmaPharm, a company that developed pharmaceutical products and technology and that had collaborated with King (and Mutual) in the past, sued Defendants (DPP Compl. ¶¶ 241-43; IPP Compl. ¶¶ 239-41; EPP Compl. ¶¶ 235-37). In the complaint, SigmaPharm alleged Defendants had engaged in a conspiracy and restrained trade in violation of the Sherman Act

[7] As an aside, Plaintiffs note Mutual filed another citizen petition on May 13, 2009; Plaintiffs contend this petition was baseless (DPP Compl. ¶¶ 230-33; IPP Compl. ¶¶ 228-31; EPP Compl. ¶¶ 224-27).

and various state laws. Then, on August 2, 2010, the United States Court of Appeals for the Federal Circuit affirmed that the '102 and '128 patents in the Sandoz litigation were invalid (DPP Compl. ¶¶ 244-49; IPP Compl. ¶¶ 242-47; EPP Compl. ¶¶ 238-43). Finally, a jury decision was reached in the '566 patent litigation case involving Sandoz in which the jury determined Sandoz did not infringe the '566 patent and the '566 patent was invalid (DPP Compl. ¶¶ 250-53; IPP Compl. ¶¶ 248-51; EPP Compl. ¶¶ 244-47).

Plaintiffs allege, but for Defendants' unlawful conduct, a generic metaxalone product would have been released prior to April 9, 2010 (DPP Compl. ¶¶ 254-60; IPP Compl. ¶¶ 252-58; EPP Compl. ¶¶ 248-51). They also allege Mutual would have entered the market with generic metaxalone but for Defendants' unlawful conduct. Finally, Plaintiffs contend Defendants' conduct forced them to pay substantial overcharges to purchase metaxalone during the relevant class periods.

V. DISCUSSION

Defendants seek to dismiss the claims raised by all three classes of Plaintiffs on five grounds. First, Defendants contend Plaintiffs' federal joint conduct claims must be dismissed because Plaintiffs have failed to plausibly allege facts establishing antitrust injury and have not overcome Defendants' immunity to antitrust liability under the *Noerr-Pennington* doctrine. Second, Defendants seek dismissal of the Indirect Purchaser Plaintiffs' claim brought pursuant to the Tennessee Trade Practices Act on the ground that the Indirect Purchaser Plaintiffs did not allege sufficient facts to establish Defendants' conduct had "substantial effects" on Tennessee trade and commerce. Third, Defendants argue the majority of the Indirect Purchaser Plaintiffs and the End Payor Plaintiffs' unjust enrichment claims must be dismissed. Fourth, Defendants claim Plaintiffs'

federal Sherman Act claims and most of the state law claims fall outside of the applicable statutes of limitations. Finally, Defendants contend Plaintiffs' allegations of fraudulent concealment are insufficient to toll the applicable statutes of limitations. The Court will address each issue in turn.

A. Federal Joint Conduct Claims

Defendants seek dismissal of Plaintiffs' federal joint conduct claims on the grounds that Plaintiffs failed to adequately allege an antitrust injury and Defendants are immune from liability under the *Noerr-Pennington* doctrine. The federal claims at issue pertain to alleged violations of the Sherman Act, 15 U.S.C. §§ 1 *et seq.*, specifically, § 1 for the restraint of trade and § 2 for conspiracy to monopolize. The claims in the complaints that correspond to these Sherman Act violations are Claims II and III of the Direct Purchaser Plaintiffs' complaint and Claim I of the End Payor Plaintiffs' complaint.[8] At issue are the four core allegations of anticompetitive conduct discussed in the complaints: (1) the '566 patent litigation involving King and Sandoz; (2) the '102 patent litigation involving King and Mutual; (3) the FDA citizen petitions filed by King and Mutual; and (4) the alleged "agreement" between King and Mutual. Defendants argue each of these "legal theories" warrant dismissal.

Plaintiffs, on the other hand, argue they have adequately alleged an overarching conspiracy or anticompetitive scheme involving Defendants and have adequately pleaded an antitrust injury cognizable under § 1 and § 2 of the Sherman Act. While they acknowledge many of Defendants'

[8] In addition to the federal joint conduct claims, Defendants also seek to dismiss Counts III and IV of the End Payor Plaintiffs' complaint, which allege nearly identical antitrust violations under state law for the restraint of trade and conspiracy to monopolize. Plaintiffs concede, and Defendants do not dispute, that the state antitrust laws at issue follow federal law (Court File No. 102 at 54 n.101). Therefore, the Court's decision on the federal claims will apply equally to the End Payor Plaintiffs' state law antitrust claims for purposes of this motion.

acts are independently anticompetitive and unlawful, they primarily argue the allegations as a whole plausibly set forth an anticompetitive scheme. Plaintiffs further argue Defendants' sham litigation and petitioning efforts are not protected from antitrust liability.

1. Antitrust Injury

Defendants argue Plaintiffs have not plausibly alleged the challenged conduct caused an actual injury under § 1 or § 2 of the Sherman Act. Section 1 of the Sherman Act provides "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States . . . is declared to be illegal." 15 U.S.C. § 1. "The essential elements of a violation of Section 1 of the Sherman Act are: (1) a contract, combination or conspiracy; (2) affecting interstate commerce; (3) which imposes an 'unreasonable' restraint of trade." *White & White, Inc. v. Am. Hosp. Supply Corp.*, 723 F.2d 495, 504 (6th Cir. 1983) (citing *Richter Concrete Corp. v. Hilltop Concrete Corp.*, 691 F.2d 818, 827 (6th Cir. 1982) and *Davis-Watkins Co. v. Serv. Merch.*, 686 F.2d 1190, 1195-96 (6th Cir. 1982)). Section 2 of the Sherman Act makes it unlawful for any person to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States." 15 U.S.C. § 2. To establish a conspiracy to monopolize, the plaintiff must be able to show "both an existence of conspiracy and specific intent to monopolize." *Richter Concrete Corp.*, 691 F.2d at 827.

Even if a violation has been established, to recover damages under § 4 of the Clayton Act or to obtain injunctive relief under § 16 of the Clayton Act, the plaintiff must be able to establish, *inter alia*, an "antitrust injury." *See Valley Products Co. v. Landmark, a Div. of Hospitality Franchise Sys., Inc.*, 128 F.3d 398, 402-03 (6th Cir. 1997). An antitrust injury is an "injury of the

type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). In defining an "antitrust injury," the court should consider two separate issues: "First, the claimed injury must be of a type that the antitrust laws were meant to discourage. And second, the plaintiff's injury must be causally related to the defendant's anti-competitive acts." *In re Cardizem I*, 105 F. Supp. 2d 618, 646 (E.D. Mich. 2000) (quoting William C. Holmes, *Antitrust Law Handbook* § 803[1][a] at 791 (1999)).

"The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation. It should, in short, be 'the type of loss that the claimed violations . . . would be likely to cause.'" *Brunswick Corp.*, 429 U.S. at 489 (citing *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 125 (1969)). Finally, the purpose of the antitrust injury requirement is to "'ensur[e] that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place,' and, more specifically, it 'ensures that a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior.'" *In re Cardizem II*, 332 F.3d. 896, 909-10 (6th Cir. 2003) (quoting *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 342-43 (1990)).

Here, even assuming Plaintiffs had adequately alleged violations of § 1 and § 2 of the Sherman Act (which Defendants do not concede), Defendants argue Plaintiffs' antitrust claims must be dismissed because Plaintiffs failed to plausibly plead Defendants' anticompetitive acts caused injury. The Court will discuss whether Plaintiffs have adequately pleaded an antitrust injury. However, as a preliminary matter, the Court must first address Defendants' contention that each of the alleged anticompetitive acts must be considered in isolation--an argument Plaintiffs fervently

dispute.

In *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962), the Supreme Court addressed whether it was appropriate to consider the plaintiffs' claims individually or in the aggregate. The Supreme Court observed the court of appeals improperly treated the plaintiffs' Sherman Act allegations as though "they were five completely separate and unrelated lawsuits," and explained "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Id.* Moreover, the Court indicated "[t]he character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole." *Id.* Numerous courts have relied on this language from *Continental Ore* to support their decision to view a plaintiff's factual allegations pertaining to a conspiracy or anticompetitive scheme in the aggregate. *See, e.g., In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at *16-17 (D. N.J. Aug. 28, 2009) (deciding not to "determine whether the underlying elements of Plaintiffs' alleged scheme are violations of the antitrust laws in their own right" when Plaintiffs had adequately pleaded Defendants had engaged in a scheme to monopolize); *In re Se. Milk Antitrust Litig.*, 555 F. Supp. 2d 934, 943 (E.D. Tenn. 2008) (viewing the plaintiffs' factual allegations in support of their § 1 Sherman Act claims in the aggregate despite defendants' efforts to "parse and dismember the complaints"); *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 428 (D. Del. 2006) (assessing the defendants' conduct as a whole "when determining antitrust liability based on a collection of factual allegations").

With that said, the fact that a court can consider factual allegations as a whole does not preclude a court from considering the allegations separately when necessary. For example, in *Biovail*

Corp. Int'l v. Hoechst Aktiengesellschaft, 49 F. Supp. 2d 750, 760 (D. N.J. 1999), the district court determined it would "examine the distinct factual allegations and address defendants' specific objections, keeping in mind the allegations as a whole, as the Supreme Court has directed." As noted by the court in *Biovail*, the approach of considering some or all of the allegations separately is supported by *Continental Ore* and other cases, particularly when it "facilitate[s] an orderly evaluation of the objections raised." *Id.* at 759. *See Continental Ore*, 370 U.S. at 709-10 (considering the record and concluding, notwithstanding its prior pronouncement, that most of the individual allegations would have been sufficient to support a verdict in favor of the plaintiffs). Nor is *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346 (Fed. Cir. 1999)--the primary case relied upon by Defendants--necessarily inconsistent with the law above. In *Intergraph Corp*., the United States Court of Appeals for the Federal Circuit considered the district court's decision to view all of the plaintiffs' theories of antitrust liability collectively rather than separately. *Id.* at 1366. Rejecting this approach, the court observed, "[e]ach legal theory must be examined for its sufficiency and applicability, on the entirety of the relevant facts." *Id.* at 1367.[9] Thus, if anything, the decision in *Intergraph* lends support for the idea that independent theories of liability should be considered separately. However, the decision does not foreclose consideration of factual allegations in the aggregate when they support a broader claim of conspiracy.

[9] The court further stated it agreed with the language in *City of Groton v. Connecticut Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981) in which the United States Court of Appeals for the Second Circuit stated, *inter alia*, "we reject the notion that if there is a fraction of validity to each of the basic claims and the sum of the fractions is one or more, the plaintiffs have proved a violation of section 1 or section 2 of the Sherman Act." *Id.*

Although Plaintiffs agree that some of their allegations could support independent claims,[10] they are primarily asserting their allegations establish the existence of a conspiracy or anticompetitive scheme for purposes of their § 1 and § 2 Sherman Act claims. Taking this into account, the Court will determine whether Plaintiffs have adequately alleged an antitrust injury viewing the factual allegations as a whole. While the Court will incorporate Defendants' objections into this discussion, those objections will be viewed primarily in the context of the broader anticompetitive scheme. *See Biovail Corp.*, 49 F. Supp. 2d at 760 (deciding it would not consider whether each violation resulted in an injury but rather whether an antitrust injury had been alleged taking into account *all* of the alleged violations). Later in this memorandum, however, the Court will separately address Defendants' specific objections to Plaintiffs' sham allegations (or theories of liability) since the Court is required to determine whether the litigation and petitions at issue are immune from antitrust liability. *See United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965) (determining that conduct protected from antitrust liability "is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act").

Returning to the issue of antitrust injury, Plaintiffs contend that "but for" Defendants' anticompetitive conduct, Plaintiffs would have paid less for metaxalone prior to April 9, 2010, which is when the first generic form of metaxalone entered the market (DPP Compl. ¶ 260; EPP Compl. ¶ 268). Plaintiffs also allege that "but for" Defendants' anticompetitive conduct, Mutual would have launched its own generic metaxalone, which would have created additional price competition for the drug (DPP Compl. ¶ 259; EPP Compl. ¶ 267). Some of the unlawful conduct that occurred as

[10] As noted by the court in *Abbott Laboratories*, "Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not." 432 F. Supp. 2d at 428.

part of Defendants' broader anticompetitive scheme or conspiracy includes Defendants' abuse of the FDA Orange Book listings, the filing of baseless citizen petitions, the filing and prosecution of baseless patent litigation, and the anticompetitive agreement entered into by Defendants (*see* DPP Compl. ¶¶ 254, 309, 318; EPP Compl. ¶¶ 265, 303). As a result of Defendants' conduct, Plaintiffs allege they were injured because they had to pay overcharges in the amount of "potentially hundreds of millions of dollars" on their purchases of metaxalone (DPP Compl. ¶ 260; EPP Compl. ¶ 251).

The first issue is whether Plaintiffs' allegations as a whole fall within the type of injury that the antitrust laws were designed to prevent. Overcharges to consumers resulting from a defendant's anticompetitive conduct is one type of injury contemplated by the antitrust laws. *See In re Cardizem II*, 332 F.3d at 910 (determining an injury had been plausibly alleged where "[t]he plaintiffs are consumers of the patented drug Cardizem CD, who allege that they were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand name product, because of a *per se* illegal horizontal market restraint"); *see also In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 688 (2nd Cir. 2009) (finding an injury had been alleged where "the plaintiffs are purchasers of the defendants' product who allege being forced to pay supra-competitive prices as a result of the defendants' anticompetitive conduct"). Here, Plaintiffs--who are purchasers of metaxalone--allege Defendants' efforts to delay the entry of generic metaxalone in the market caused them to incur overcharges because they had to pay for Skelaxin, the higher-priced brand-name drug with the active ingredient metaxalone, rather than a lower-priced generic. This allegation satisfies the first requirement for alleging an antitrust injury.

The next issue and Defendants' core concern is whether Plaintiffs have adequately alleged causation. First, with respect to the King-Mutual agreement, Defendants argue Plaintiffs cannot

plausibly plead they were injured because (1) the agreement never prohibited Mutual from entering the market and (2) Plaintiffs cannot establish Mutual ever received tentative or actual FDA approval of its generic drug. Second, with respect to the '566 patent litigation, Defendants claim Plaintiffs cannot establish they were injured because the '566 litigation never resulted in a thirty-month stay. To establish a causal connection, the plaintiff must allege "*some* damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage." *In re Cardizem I*, 105 F. Supp. 2d at 649 (quoting *Zenith Radio Corp.*, 395 U.S. at 114 n.9) (emphasis added)). Thus, "[i]t is enough that the illegality is shown to be a material cause of the injury; *a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury under § 4 [of the Clayton Act]*." *Id.*

Beginning with the King-Mutual agreement, Defendants argue Plaintiffs failed to plausibly allege the agreement caused an injury because the agreement did not forbid Mutual from entering the market with a generic metaxalone product. Defendants argue the plain terms of the license agreement expressly preserve Mutual's rights to use its own intellectual property to bring generic metaxalone to market. Defendants also note that, to the extent Plaintiffs are averring there was "some other agreement" prohibiting Mutual from entering the market, the complaints fail to allege such facts. Finally, Defendants argue Plaintiffs wrongly assert King's payments to Mutual were a *quid pro quo* for Mutual's agreement to stay out of the market; instead, Defendants contend the payments were made to compensate Mutual for granting King a non-exclusive license to its intellectual property. Plaintiffs, on the other hand, argue that their allegations show Defendants' unlawful conduct, including but not limited to the actual written agreement, is causally connected to Plaintiffs' injury.

Turning to the terms of the license agreement between King and Mutual dated December 6, 2005, the Court agrees with Defendants that there are no express terms in the agreement prohibiting Mutual from entering the market with generic metaxalone (*see* Court File No. 85-7 ("Agreement")). The agreement provides that Mutual would grant King and its affiliates a "worldwide, co-exclusive (with Mutual) license under the Licensed Patent Rights and under the Licensed Know-How, in each case to make, use, offer for sale, sell and import Licensed Products" (*id.* § 2.1(a)). The "Licensed Patent Rights" and "Licensed Know-How" referenced in the agreement include the in vitro enzyme studies[11] and in vivo patent rights owned or controlled by Mutual (*id.* §§ 1.12, 1.13). King also granted to Mutual a "worldwide, non-exclusive license under any and all In Vivo Know-How and In Vivo Patent Rights owned or controlled by [King], solely to make, use, offer for sale, sell, and import any products, kits or methods other than Licensed Products" (*id.* § 2.1(b)). As part of the agreement, King agreed to make a "one-time, up-front payment to Mutual of US $35,000,000" and King further agreed to pay Mutual royalties on net sales (*id.* § 3.1). The actual percentages or amounts that Mutual would receive in royalties over time are redacted from the agreement. Finally, the agreement allows Mutual to retain the "right . . . to prepare, file, prosecute and maintain the Licensed Patent Rights" and, under other limited circumstances, to pursue suspected infringement of its patent rights (*see id.* §§ 4.1, 4.2). In sum, the agreement on its face could be read simply as a licensing agreement between two entities in which one party is being paid a mere licensing fee--conduct that would not necessarily be unlawful.

What makes the agreement more suspect are Plaintiffs' additional allegations, both with

[11] These are presumably the metabolism studies referenced in the complaints that Mutual commissioned in 2005.

respect to the sum of payments received by Mutual and the relationship of the written agreement to the broader anticompetitive scheme. These facts nudge Plaintiffs' allegations of an anticompetitive scheme or conspiracy under either § 1 or § 2 of the Sherman Act "across the line from conceivable to plausible." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). First, Plaintiffs allege the "licensing fee" payments that King made to Mutual were not an insignificant sum (DPP Compl. ¶ 178; EPP Compl. ¶ 172). Rather, the payments made to Mutual were in excess of $200 million and were paid over a period of time. As Plaintiffs explained at the hearing, King's payments to Mutual were so large that there was no need for the agreement to expressly tell Mutual to stay off the market. Mutual and King had essentially become "copartners" for an extended period of time and Mutual shared in King's profits.[12] None of this information, however, is discernable from the face of the agreement.

In *In re Cardizem I*, the district court was confronted with the question of whether the anticompetitive effects of an agreement entered into by the defendants delayed the entry of a generic into the market and caused the plaintiffs to incur overcharges. 105 F. Supp. 2d 618 (E.D. Mich. 2000). Defendant Andrx was developing a generic version of the brand name drug Cardizem CD. *Id.* at 631. After Andrx filed an ANDA application and made a paragraph IV certification, Defendant HMRI and another entity filed a patent infringment suit against Andrx. *Id.* The plaintiffs allege Andrx could have entered the market with a generic as early as July 9, 1998, which was when the thirty-month stay would have expired. *Id.* at 632. However, in September 1997, Andrx entered into

[12] As alleged in the complaints, "Mutual's earlier incentives to challenge King's invalid patents and seek early approval of its ANDA vanished. . . . It would make more money by helping King keep other would-be competitors off the market than it could by launching its own generic metaxalone" (DPP Compl. ¶ 180; EPP Compl. ¶ 174).

an agreement with HMRI that the plaintiffs alleged had the effect and purpose of allowing the defendants to maintain their monopoly of the market and set artificially high prices. *Id.* As part of the agreement, Andrx would receive $40 million in annual payments from HMRI. *Id.* The district court concluded that the agreement and the $40 million payments were a "material cause" of Andrx's decision to not enter the market at the time it could have done so. *Id.* at 650. Here, although the facts are not identical,[13] Plaintiffs have similarly alleged the agreement, especially given the size of the payments to Mutual, had the effect and purpose of keeping Mutual from entering the market with generic metaxalone.

The Court notes Plaintiffs have alleged additional facts to demonstrate the agreement was part of a larger anticompetitive scheme or conspiracy. For instance, two months prior to King and Mutual entering into the written agreement, Plaintiffs allege some of King and Mutual's top executives participated in a secret meeting (DPP Compl. ¶ 175; EPP Compl. ¶ 169). At the meeting, King indicated it intended to make substantial annual payments to the generic companies threatening King's monopoly, specifically companies with which King was embroiled in patent litigation. Then, after the agreement was executed, Defendants proceeded to engage in anticompetitive acts including but not limited to maintaining sham patent litigation cases and filing sham citizen petitions (DPP Compl. ¶¶ 181-253; EPP Compl. ¶¶ 175-247). All of these acts together, according to Plaintiffs, had the effect of delaying the entry of a generic into the market until 2010 (DPP Compl. ¶¶ 261-71; EPP Compl. ¶¶ 263-75). And as a result, Plaintiffs allege they were forced to pay substantially more for metaxalone than they would have had a generic metaxalone product been able to enter the market

[13] Defendants contend the agreement in *In re Cardizem I* expressly precluded Andrx from entering the market.

sooner (*id.*).

The allegations in the instant complaints set this case apart from the allegations in *Twombly*, where the plaintiffs were unable to plausibly allege a conspiracy. As noted earlier, in *Twombly*, the plaintiffs' complaint contained primarily allegations of the defendants' parallel conduct. 550 U.S. at 664. While the complaint contained "a few statements" alleging an agreement, the Supreme Court determined those statements were "merely legal conclusions resting on the prior allegations," *id.* at 564-65, and that the plaintiffs' § 1 claim was not adequately pleaded, *id.* at 570. In contrast, and as noted by Plaintiffs at the hearing, in the instant case we not only have an alleged written and unwritten agreement between the parties but other alleged anticompetitive acts stemming from the agreement(s). Together, these facts demonstrate more than just parallel conduct; they support the existence of a conspiracy or anticompetitive scheme. *See SigmaPharm, Inc. v. Mutual Pharmaceutical Co., Inc.*, 772 F. Supp. 2d 660, 670-72 (E.D. Pa. 2011) (considering essentially the same set of facts now presently before this Court and concluding the plaintiff SigmaPharm had plausibly alleged an agreement in restraint of trade in violation of § 1 of the Sherman Act when viewing the facts as a whole). From these facts, the Court can also reasonably infer that Defendants' unlawful conduct was a "material cause" of the overcharges incurred by Plaintiffs.

Defendants, however, contend there are additional reasons the Court should conclude Plaintiffs have failed to adequately plead causation. Defendants contend Plaintiffs cannot establish the agreement between King and Mutual harmed Plaintiffs because they cannot show the FDA ever granted tentative or final approval of Mutual's generic drug. Defendants argue it was not a foregone conclusion that Mutual's generic metaxalone would have received tentative or final FDA approval. At this early stage of the proceedings, however, Plaintiffs are not required to "adduce proofs

discrediting all possible intervening causes of the delayed launch of generic products, such as the failure to obtain tentative generic approval from the FDA before the expiration of the 30-month stays at issue." *In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at *12. *See In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 756-57 (E.D. Pa. 2003) (concluding plaintiffs had plausibly alleged defendants' frivolous lawsuits "materially caused" plaintiffs' injury despite defendants' alternate theory that the real reason for the delay was plaintiffs' failure to obtain FDA approval); *see also In re Cardizem I*, 105 F. Supp. 2d at 650 (noting plaintiffs did not have to disprove every "hypothetical possibility" to establish antitrust injury). Additional discovery may reveal Mutual would not have pursued its ANDA application even if it had not entered the conspiracy. It might also reveal Mutual's generic metaxalone product was not of the caliber to obtain FDA approval. These questions, however, are issues of fact that need not be resolved at this stage. Because Plaintiffs are not required to eliminate all possible alternative sources of injury to plead causation, the Court will disregard Defendants' objection on this basis.

Finally, Defendants dispute whether Plaintiffs can establish causation for the '566 patent litigation because the case was never subject to a thirty-month stay. The reason it was not subject to a thirty-month stay was because Sandoz's ANDA application was filed before the PTO issued the '566 patent. According to Defendants, the fact that there was no thirty-month stay demonstrates the patent litigation could not have delayed market entry. As noted by Plaintiffs, however, Defendants cannot point to any case law that says a party is automatically foreclosed from bringing a sham litigation claim simply because the litigation is not subject to a thirty-month stay. Moreover, Plaintiffs actually do allege in their complaints that the '566 litigation caused a delay albeit for a different reason (DPP Compl. ¶¶ 237-40; EPP Compl. ¶¶ 231-34). Because King sought to enjoin

Sandoz from immediately launching its product after it received FDA approval, Plaintiffs allege Sandoz was delayed from entering the market by at least nine days. Lastly, the Court can reasonably infer that the misuse of the litigation process can impose additional cost and time barriers on the generic manufacturer that could further delay it from entering the market. Thus, the absence of a thirty-month stay in the '566 patent litigation is not so damaging at this stage that it inhibits Plaintiffs from plausibly alleging causation.

Accordingly, for all of the reasons stated above, the Court concludes Plaintiffs have plausibly alleged an antitrust injury.

2. *Noerr-Pennington* Immunity

Defendants argue most of the conduct alleged to be unlawful in this case is actually protected from antitrust liability under the *Noerr-Pennington* doctrine. At issue is the '102 patent litigation, the '566 patent litigation, and the various FDA citizen petitions filed by Defendants. This analysis is important, among other reasons, because it can affect whether the sham allegations can be considered part of the anticompetitive scheme. *See Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 430 (D. Del. 2006) (stating the plaintiffs "may not use litigation conduct to support a claim of an overall scheme to monopolize if they cannot prove that the litigation was a sham"); *see also In re Neurontin Antitrust Litig.*, MDL 1479, 2009 WL 2751029, at *17 (D. N.J. Aug. 28, 2009) (noting "conduct protected by *Noerr-Pennington* immunity cannot be properly included within the scope of the monopolization scheme alleged" (citing *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965))).

In *Eastern R. R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961), the Supreme Court asserted in light of prior precedent that "where a restraint upon trade or

monopolization is the result of valid governmental action, as opposed to private action, no violation of the Act can be made out." *Id.* at 529. The Court further declared "[w]e think it equally clear that the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly." *Id.* The Sherman Act would be applicable, however, under the narrow circumstances where the conduct is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Id.* at 144. These principles were reaffirmed in *United Mine Workers v. Pennington*, 381 U.S. 657 (1965). *Id.* at 670 ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act.").

Below the Court will discuss the doctrine that emerged from *Noerr* and *Pennington* as applied to the allegations of sham litigation and sham petitioning in this case.

a. Sham Patent Litigation

Defendants argue Plaintiffs' claims should be dismissed with respect to the '102 patent litigation involving King and Mutual and the '566 patent litigation involving King and Sandoz because neither case was a sham. In *Prof'l Real Estate Investors, Inc. ("PRE") v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993), the Supreme Court articulated a two-part standard that must be applied when determining whether the *Noerr* sham exception applies.

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham,

> the court should focus on whether the baseless lawsuit conceals "an attempt to interfere *directly* with the business relationships of a competitor," *Noerr, supra*, 365 U.S., at 144[,] 81 S.Ct., at 533 (emphasis added), through the "use [of] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon," *Omni*, 499 U.S., at 380, 111 S.Ct., at 1354 (emphasis in original).

Id. at 60-61. Hence, the plaintiff must first establish the suit was "objectively baseless"; only after the first step has been established may the court consider the defendant's subjective motivation. *See In re Cardizem I*, 105 F. Supp. 2d 618, 643 (E.D. Mich. 2000). Stated differently, the plaintiff must "disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability." *PRE*, 508 U.S. at 61. Moreover, even if the plaintiff can prove both elements to demonstrate the litigation was a sham and overcome the defendant's antitrust immunity, the plaintiff must still prove the defendant committed a substantive antitrust violation. *Id.* at 61.

i. '102 Patent Litigation

Defendants contend Plaintiffs have failed to plausibly allege the '102 patent litigation involving King and Mutual was objectively baseless or subjectively filed and maintained in bad faith. In particular, they argue King and Mutual's request to stay the case was simply a petition to the court and therefore immune from liability. They further argue challenging a motion to stay as being a sham is unprecedented. Plaintiffs, on the other hand, argue their pleadings demonstrate the '102 patent litigation as a whole was a sham and that the motion to stay was just one part of the sham.

Taking the allegations in the complaint as true and viewing them in the light most favorable to Plaintiffs, the Court concludes Plaintiffs have adequately satisfied the first prong of the *PRE* test. To demonstrate the litigation is objectively baseless, Plaintiffs must allege facts demonstrating that no litigant would believe "the suit is reasonably calculated to elicit a favorable outcome." *See PRE*,

508 U.S. at 60. Here, Plaintiffs allege the '102 patent was issued in January 2004 and was "directed to methods of providing metaxalone to patients while informing them that taking metaxalone with food results in higher blood levels of metaxalone" (DPP Compl. ¶¶ 129-30; EPP Compl. ¶¶ 123-24). However, according to Plaintiffs, the '102 patent suffered from problems similar to those in the '128 patent--that is, "the claims in the '102 patent were invalid for anticipation by the prior art and for obviousness" (DPP Compl. ¶ 131; EPP Compl. ¶ 125). In other words, Plaintiffs believed, *inter alia*, the '102 patent lacked novelty and that the results of a study about taking metaxalone with food could not be patented because the benefits of doing so were already well known (DPP Compl. ¶¶ 132-34; EPP Compl. ¶¶ 126-28). Plaintiffs further allege King's filing of the '102 litigation against Mutual "was a sham, at least for the same reasons that the Eon '128 and CorePharma '128 litigations were baseless. No reasonable practitioner would conclude the patentee to have a realistic likelihood of prevailing on the merits" (DPP Compl. ¶ 140; EPP Compl. ¶ 134). Plaintiffs also highlight the fact that even Mutual mentioned in its notice to King after it made its paragraph IV certification--and prior to Mutual entering into the agreement with King--that any litigation brought with respect to the '102 patent would be baseless (*see* DPP Compl. ¶ 137; EPP Compl. ¶ 131).

Moreover, contrary to Defendants' arguments, Plaintiffs' allegations with respect to the motion to stay further support the contention that the litigation was objectively baseless and need not be treated as a separate sham allegation. Plaintiffs allege that, during the course of the litigation, King and Mutual filed a motion to stay the proceedings pending the FDA's decision on King's 2004 citizen petitions (DPP Compl. ¶¶ 192-95; EPP Compl. ¶¶ 186-89). Filing a motion is a normal part of the litigation process and would ordinarily not be a cause of concern. However, according to Plaintiffs, the issue here was that when the motion to stay was filed there was no longer a

"justiciable controversy" because King and Mutual had already entered into their agreement and the pending FDA decision would not have had any impact on the case (DPP Compl. ¶¶ 196-202; EPP Compl. ¶¶ 190-96).

This leads to the second prong of the *PRE* test--that is, whether Defendants subjectively acted in bad faith. Taking Plaintiffs' allegations as true, Plaintiffs have plausibly alleged the '102 litigation was just one part of King's larger monopolistic scheme to delay the entry of a generic into the market, and the motion to stay was further evidence of the conspiracy or anticompetitive scheme between King and Mutual (DPP Compl. ¶¶ 192-202; EPP Compl. ¶¶ 186-96). For instance, Plaintiffs succinctly allege "[w]hile the Mutual '102 litigation had been a sham from the outset (as it had no likelihood of success), with Mutual's complicity in it, the case was now a concerted fraud on the court. Although there was no longer any justiciable controversy, both parties continued the litigation for an additional five years as a subterfuge to maintain their outward appearances--to the FDA, the FTC, and the public--as adversaries rather than conspirators" (DPP Compl. ¶ 200; EPP Compl. ¶ 194).

Plaintiffs will not have an easy task trying to prove both prongs of the *PRE* test as the case progresses. Yet, at this stage, the Court must view the facts alleged in the complaints in the light most favorable to Plaintiffs. Therefore, taking into account Plaintiffs' allegations with respect to the '102 patent litigation--particularly Plaintiffs' allegation that King and Mutual committed a fraud on the court and the public--as well as Plaintiffs' allegations regarding the broader conspiracy, the Court concludes Plaintiffs have plausibly alleged the litigation was a sham to overcome Defendants' antitrust immunity.

ii. '566 Patent Litigation

Defendants also argue Plaintiffs have failed to establish the '566 patent litigation involving King and Sandoz was a sham. Defendants contend Plaintiffs fail to allege anything more than "conclusory allegations" regarding the subjective bad faith prong. Defendants contend it is implausible for Plaintiffs to allege Defendants brought suit with any purpose other than to prevail on the merits. In support of this argument, they argue that--unlike in the context of the '102 patent litigation--because Sandoz filed its ANDA application prior to the issuance of the '566 patent, the litigation would not be subject to the thirty-month automatic stay. Thus, Defendants contend they would not have brought the suit unless they had reasonably believed they had a chance at prevailing. Plaintiffs, on the other hand, contend Defendants filed the '566 patent litigation in bad faith and the litigation was just part of Defendants' larger scheme to delay the entry of a generic form of metaxalone in the market. They also aver the '566 litigation actually did cause a delay, though not in the form of a thirty-month stay.

Because Defendants only contest the second prong of the *PRE* test in their motion, the Court will presume for purposes of this motion only that the first prong was adequately alleged. With respect to the second prong, the Court must determine whether Plaintiffs have plausibly alleged the suit was "an attempt to interfere directly with the business relationships of a competitor." Here, Plaintiffs allege Defendants' efforts to file and maintain the '566 patent litigation were just part of the larger anticompetitive scheme to prevent Sandoz or any other competitor from entering the market sooner. Even if Defendants knew Sandoz was not subject to a thirty-month stay, Defendants were certainly aware--as was the case in the '102 patent litigation--that the litigation process could be used as a tool for delay. Here, this was most apparent with respect to the circumstances surrounding the FDA's approval of Sandoz's ANDA application (DPP Compl. ¶¶ 234-40; EPP

Compl. ¶¶ 228-34). Sandoz was preparing for an immediate launch after receiving FDA approval, but Defendants sought to enjoin Sandoz's launch, which resulted in a nine-day delay of Sandoz's generic metaxalone product into the market. Admittedly, filing a motion for injunctive relief is not inherently an act taken in bad faith and this is not Plaintiffs' strongest argument. However, the facts surrounding the '566 litigation combined with the other sham litigation and conspiracy allegations are sufficient at this stage to overcome *Noerr-Pennington* immunity.

b. Sham Citizen Petitions[14]

Finally, Defendants argue Plaintiffs have failed to plausibly allege the FDA citizen petitions filed by King and Mutual were, in fact, sham petitions. First, Defendants contend the two-part test created in *PRE* to assess whether the "sham" exception applies is only relevant in the context of adjudications. Defendants contend filing petitions with the FDA in the instant context is not adjudicatory. Moreover, even if *PRE* did apply, Defendants claim Plaintiffs would be unable to show the petitions were "objectively baseless." Plaintiffs, on the other hand, argue the *PRE* test is just as applicable to administrative actions as it is to court proceedings. Moreover, even if *PRE* only applied to adjudications, the FDA process at issue is similar enough to an adjudication that the *PRE* test

[14] Defendants also argue Plaintiffs' claims pertaining to the citizen petitions are blocked pursuant to statute and under the applicable statute of limitations. With regard to the statute, Defendants point out that Section 505(q) of the FDCA states a pending citizen petition "shall not delay approval of a pending [ANDA]" unless the FDA determines the "delay is necessary to protect public health" (Court File No. 85 at 37). This policy went into effect September 27, 2007. Therefore, according to Defendants, any petitions filed after this date would not have delayed the approval process. Plaintiffs, however, allege in their complaint that this system was not foul-proof. In fact, they even allege the FDA acknowledged in its March 2010 approval letter of Sandoz's ANDA that its delay was due in part to the citizen petitions filed by Defendants (DPP Compl. ¶ 262; EPP Compl. ¶ 264). Thus, there is a factual dispute regarding the effectiveness of the changes brought by Section 505(q) of the FDCA that need not be resolved at this time. Defendants also argue any petitions filed before September 2007 are outside the statute of limitations. Arguments pertaining to the statute of limitations, however, will be addressed later in this memorandum.

should apply. Finally, under either standard, Plaintiffs contend the *PRE* test would be satisfied.

As a preliminary matter, it is undisputed the *Noerr-Pennington* doctrine can apply to both judicial proceedings and administrative agency actions. *See California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (noting the *Noerr-Pennington* doctrine also "governs the approach of citizens or groups of them to administrative agencies (which are both creatures of the legislature, and arms of the executive) and to courts, the third branch of Government. Certainly the right to petition extends to all departments of the Government. The right of access to the courts is indeed but one aspect of the right of petition.").[15]

Defendants, nonetheless, argue the sham exception articulated in *Noerr*--and the focus of the two-part test in *PRE*--should not be applied in the context of FDA citizen petitions because the citizen petition process is not adjudicatory in nature. Defendants cite *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056 (9th Cir. 1998), for the proposition that the *PRE* test should only be applied in the administrative context if the agency is acting more like an adjudicative body than a quasi-legislative body. In *Kottle*, the United States Court of Appeals for the Ninth Circuit considered whether the *Noerr-Pennington* doctrine applied to lobbying efforts directed at influencing a state administrative agency to issue a certificate of need for a healthcare facility. *Id.* at 1059. While the Ninth Circuit determined the organization's lobbying activities implicated the *Noerr-Pennington* doctrine, the more challenging question was whether the sham exception applied. *Id.* at 1059-60. The court

[15] Citing *Potters Med Ctr. v. City Hosp. Ass'n*, 800 F.2d 568, 578 (6th Cir. 1986), Defendants claim the Supreme Court "recognized that 'unethical conduct in the setting of the adjudicatory process' . . . is unprotected by the *Noerr-Pennington* doctrine." *Id.* at 578 (quoting *California Motor Transp. Co.*, 404 U.S. at 510). However, in attempting to narrow the scope of the application of the *PRE* test to just adjudicatory proceedings, Defendants neglect to mention their quote comes from *California Motor*, and the redacted portion expressly mentions agency proceedings.

concluded the proper inquiry should be "whether the executive entity in question more resembled a judicial body, or more resembled a political entity." *Id.* at 1061. The court further explained that, in the absence of clear guidance from the Supreme Court for scenarios outside the judicial context, its understanding was that "executive entities are treated like judicial entities only to the extent that their actions are guided by enforceable standards subject to review." *Id.* at 1062. *See St. Joseph's Hosp., Inc. v. Hosp. Corp. of Am.*, 795 F.2d 948, 955 (11th Cir. 1986).

Several courts, however, confronted with the specific question of whether the sham exception applies to an FDA citizen petition have concluded the sham exception applies. *See In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 309-10 (E.D. Pa. 2011) (denying the defendant's motion for summary judgment after applying the two-pronged test from *PRE* in the context of FDA citizen petitions; citing other cases, the court noted the test has generally been applied to administrative agencies); *see also In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (applying the *PRE* test in the context of an FDA citizen petition). *Cf. Cheminor Drugs., Ltd. v. Ethyl Corp.*, 168 F.3d 119 (3d Cir. 1999) (applying the *PRE* test in the broader context of a petition filed by a drug manufacturer with the Department of Commerce and the U.S. International Trade Commission); *In re Cardizem I*, 105 F. Supp. 2d at 644 (concluding the defendants' communications with the FDA regarding the scope of the right of reference were subject to the sham exception and determining Plaintiffs pleaded sufficient facts to satisfy the two-part *PRE* test).

Moreover, in *In re Prograf Antitrust Litig.*, 1:11-MD-2242-RWZ, 2012 WL 293850, at *5 (D. Mass. Feb. 1, 2012), the district court expressly rejected the distinction made by the Ninth Circuit in *Kottle*. In explaining its reasoning, the court noted "if the sham exception applied only to

adjudicative processes, then any act of advocacy before a legislative or quasi-legislative body would be shrouded in carte blanche immunity regardless of purpose or sufficiency--even if the activity was utterly baseless, an abuse of process, and motivated solely to stifle competition"; the court observed this would be contrary to the purposes of *Noerr* and its progeny. *Id.* The court further noted that no courts, including *Kottle*, have gone so far as to hold the sham exception is "categorically unavailable when agencies are petitioned in their 'quasi-legislative' and not their 'adjudicatory' capacity." *Id.* Finally, the court observed that, even if the distinction applied, the FDA citizen petition process was sufficiently adjudicatory in nature that the sham exception should be applied. *Id.*

Here, in the absence of any binding Supreme Court or Sixth Circuit authority on the subject, the Court is swayed by the arguments made by the courts directly confronted with the question of whether the sham exception applies in the context of the FDA citizen petition process. The aforementioned courts all concluded the sham exception should be applied. Accordingly, applying the *PRE* two-part test, Plaintiffs have plausibly alleged facts to demonstrate Defendants' petitions viewed in the aggregate were objectively baseless and filed subjectively in bad faith. Plaintiffs have alleged a series of petitions were filed by King and Mutual to delay approval of generic metaxalone. For example, Plaintiffs allege in 2004 King filed a petition requesting that the FDA reconsider its decision allowing generic manufacturers to carve out the "food effects" information from their metaxalone labels (DPP Compl. ¶¶ 142, 147-54; EPP Compl. ¶¶ 136, 141-48). Although Plaintiffs allege King's objections to the FDA decision were baseless, King sought a stay of the approval of any generic metaxalone drugs until the FDA had ruled on its citizen petition. Then, in 2005, Mutual filed a petition for the FDA to reconsider the March 2004 decision just days after signing the King-Mutual agreement (DPP Compl. ¶¶181-85; EPP Compl. ¶¶ 175-79). Mutual's petition, however,

would have been contrary to its interests had it actually been pursuing approval of its ANDA application. Finally, between 2007 and 2009, Mutual and King filed at least five more petitions with the FDA (DPP Compl. ¶¶ 206-33; EPP Compl. ¶¶ 200-27). With respect to each of these petitions, Plaintiffs allege Defendants failed to include clinical studies demonstrating actual clinical effects, which is the type of information the FDA generally relies upon. Moreover, Plaintiffs allege each of these petitions was a sham and filed only to further delay the entrance of generic metaxalone into the market. Particularly relevant here are the words of the Supreme Court in *California Motor*:

> One claim, which a court or agency may think baseless, may go unnoticed; but a *pattern of baseless, repetitive claims* may emerge which leads the factfinder to conclude that the administrative and judicial processes have been abused. That may be a difficult line to discern and draw. But once it is drawn, the case is established that abuse of those processes produced an illegal result, viz., effectively barring respondents from access to the agencies and courts.

California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 513 (1972) (emphasis added). In sum, viewing the facts in the light most favorable to Plaintiffs, the Court concludes Plaintiffs have plausibly alleged Defendants filed sham petitions--and as noted earlier, filed and maintained sham patent infringement cases--to further their anticompetitive scheme. Accordingly, Defendants are not protected from antitrust immunity under the *Noerr-Pennington* doctrine and Plaintiffs' sham allegations will survive Defendants' motion to dismiss.

B. Tennessee Trade Practices Act

Defendants seek dismissal of the Indirect Purchaser Plaintiffs' Tennessee Trade Practices Act ("TTPA") claim on the ground that Plaintiffs failed to plausibly allege Defendants' conduct had "substantial effects" on Tennessee trade or commerce. In particular, Defendants argue all of the proposed class members are non-residents of Tennessee and the sales at issue were all made outside of Tennessee. The Indirect Purchaser Plaintiffs, however, argue the TTPA would apply to non-

resident indirect purchasers so long as Defendants' conduct affected Tennessee trade or commerce to a "substantial degree." They contend their complaint satisfies this requirement.

The parties agree the leading case on this matter is *Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512 (Tenn. 2005). In *Freeman*, the plaintiff Freeman Industries, LLC, a non-resident of Tennessee who was an indirect purchaser of sorbates, alleged one of the defendants, Eastman Chemical Company who had its principal place of business in Tennessee, was engaged in a price-fixing conspiracy involving the sale of sorbates. *See id.* at 516. The Tennessee Supreme Court discussed the TTPA[16] and its applicability to indirect purchasers, noting the statute did not "prohibit recovery to indirect purchasers who are non-residents of Tennessee." *Id.* at 517. After emphasizing that the focus should be on the "effect" of the defendant's anticompetitive conduct on Tennessee trade or commerce rather than the defendant's anticompetitive "conduct," the court explained the proper standard to apply is the "substantial effects" standard. *Id.* at 523. Under the "substantial effects" standard, a court "must decide whether the alleged anticompetitive conduct affects Tennessee trade or commerce to a substantial degree." *Id.* "The determination of whether an effect is substantial does not involve 'mathematical nicety'" but instead "turn[s] upon the particular

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[16] The TTPA expressly provides:

> All arrangements, contracts, agreements, trusts, or combinations between persons or corporations made with a view to lessen, or which tend to lessen, full and free competition in the importation or sale of articles imported into this state, or in the manufacture or sale of articles of domestic growth or of domestic raw material, and all arrangements, contracts, agreements, trusts, or combinations between persons or corporations designed, or which tend, to advance, reduce, or control the price or the cost to the producer or the consumer of any such product or article, are declared to be against public policy, unlawful, and void.

Tenn. Code Ann. § 47-25-101.

facts of the case." *Id.* Moreover, the alleged anticompetitive conduct "need not threaten the demise of Tennessee businesses or affect market prices to substantially affect intrastate commerce." *Id.* at 523-24.

Applying the substantial effects standard to the facts before it, the Tennessee Supreme Court determined Freeman's claims did not fall within the scope of the TTPA. The court observed Freeman's bare allegations that Eastman "took orders and implemented sales to customers at the new prices from Tennessee" and that Eastman's conduct "resulted in Freeman paying higher prices to retailers for items containing sorbates" were insufficient to establish Tennessee commerce was substantially affected. *Id.* at 524. In particular, the court highlighted the fact that there was no evidence the items purchased by Freeman contained any of the sorbates manufactured by Eastman; this was significant because Eastman was the only defendant with Tennessee connections. *Id.*

Although *Freeman* makes clear that the TTPA can apply to non-resident indirect purchasers, Defendants contend the Indirect Purchaser Plaintiffs here are not only non-residents but they are also non-residents who have no business ties to the Tennessee pharmaceutical market. Although Defendants attempt to redirect the Court's attention toward the conduct of the Indirect Purchaser Plaintiffs, the statute as explained in *Freeman* is primarily focused on the substantial effect of *Defendants'* conduct on Tennessee's commerce. The Indirect Purchaser Plaintiffs readily admit they are non-resident pharmacies and other purchasers for resale who were forced to pay more for metaxalone products due to Defendants' unlawful conduct (IPP Compl. ¶ 301). Specifically, they contend Defendants entered into an unlawful agreement to restrain trade, which had the effect of delaying entry of generic metaxalone in the market until 2010. The Indirect Purchaser Plaintiffs also allege a number of facts in their complaint to highlight King's ties to Tennessee and the effect of

Defendants' unlawful conduct on the state (IPP Compl. ¶¶ 283-84). Most notably, the Indirect Purchaser Plaintiffs allege King had its corporate headquarters and principal place of business in Tennessee and operated "a centralized branded prescription distribution center and manufacturing facilities" in Tennessee. Moreover, until April 2010, King was the sole manufacturer of metaxalone in the market. Thus, unlike in *Freeman* where it was unclear whether the plaintiff's purchases of sorbates had a "substantial" effect on Tennessee given that several other defendants manufactured sorbates outside of Tennessee, here the Indirect Purchaser Plaintiffs have alleged the overcharges they paid all flowed back to Tennessee because King was the sole seller.

At oral arguments, Defendants claimed the Indirect Purchaser Plaintiffs could not demonstrate the alleged effects were "substantial" because not all of the money from Skelaxin sales went to King. Any dispute surrounding this issue, however, is an issue of fact that can be explored further during the course of discovery.[17] Viewing the facts at this stage in the light most favorable to the Indirect Purchaser Plaintiffs, the complaint adequately alleges the Indirect Purchaser Plaintiffs paid possibly hundreds of millions of dollars in overcharges and--even taking into account other entities in the chain of production such as the wholesaler and supplier--King most likely received a significant portion of the sales. Moreover, given that King conducted business out of Tennessee, the Court can reasonably infer that a substantial portion of that money flowed back to Tennessee. Finally, taking the Indirect Purchaser Plaintiffs' allegations as true regarding the nature of the agreement between King and Mutual, it is also plausible that some or all of the money that went toward Mutual to further Defendants' anticompetitive scheme had the effect of depriving the state

[17] When questioned by the Court at the hearing, even Defendants' counsel admitted he could not say offhand how much King actually received from its Skelaxin sales.

of Tennessee of additional funds. All of these acts would have affected intrastate commerce.[18]

Accordingly, the Court will deny Defendants' motion with respect to the Indirect Purchaser Plaintiffs' TTPA claim.

C. Unjust Enrichment

Defendants aver Claim VIII of the Indirect Purchaser Plaintiffs' complaint and Claim VI of the End Payor Plaintiffs' complaint alleging unjust enrichment must be dismissed. First, Defendants contend there is no federal common law of "unjust enrichment." Moreover, they argue Plaintiffs are attempting to skirt various states' antitrust and consumer protection laws by filing unjust enrichment claims. Finally, with respect to the Indirect Purchasers, Defendants argue that, to the extent the Indirect Purchasers are asserting state unjust enrichment claims, they failed to name the state laws at issue in their complaint.

In their response, Plaintiffs clarify that neither is asserting a federal common law claim of unjust enrichment. Rather, their claims are based on state law. Plaintiffs further contend their unjust

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[18] Finally, the Court observes that a number of cases cited by Defendants can be distinguished from the facts of the instant case. For instance, in *In re Magnesium Oxide Antitrust Litig.*, Civ. No. 10-5943 DRD, 2011 WL 5008090, at *8 n.10 (D. N.J. Oct. 20, 2011), the district court dismissed a TTPA claim along with several other state claims because the plaintiffs' allegations were "conclusory" and "fail[ed] to specifically tie their injuries to the alleged MgO conspiracy occurring or its effects in those states." *See In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 416 (E.D. Pa. 2009) (concluding the TTPA claim must be dismissed because the plaintiffs failed to allege any substantial effects on Tennessee). However, as noted by the Indirect Purchaser Plaintiffs, those cases are not directly analogous to the instant case because neither involved a defendant who was based in Tennessee nor did the plaintiffs adequately allege the defendants' conduct had "substantial effects" on Tennessee commerce. Similarly, *Medison Am., Inc. v. Preferred Med. Sys.*, LLC, 357 F. App'x 656 (6th Cir. 2009), is also distinguishable. *Id.* at 662-63 (dismissing the plaintiff's TTPA claim at summary judgment because the only injury cited by the plaintiff, an ultrasound manufacturer, was its own, which the Sixth Circuit determined was insufficient to show a "substantial effect" on Tennessee trade or commerce).

enrichment claims can be raised as a separate cause of action without regard to whether the court finds liability on the other claims. In other words, Plaintiffs argue their claims can be pleaded generally and in the alternative. Finally, the Indirect Purchasers argue their complaint is detailed enough to put Defendants on notice of their unjust enrichment claims even if the specific state laws are not named in the complaint. They contend the exact composition of the class will not be known until class certification, at which time the Court will likely conduct a choice of law analysis and determine which states' laws should be applied. In the event their pleading is insufficient, however, the Indirect Purchasers ask that they be allowed to amend their complaint to list the state laws under which they are asserting their unjust enrichment claims.

Because neither Plaintiffs' group is asserting a federal common law claim, the Court will proceed to address Defendants' other objections. The first issue is whether, as a matter of law, Plaintiffs are precluded from asserting unjust enrichment claims because the claims are merely a means of circumventing state antitrust and consumer protection laws. Defendants argue that if Plaintiffs are unsuccessful at proving their substantive claims they should not be allowed to subsequently recast their allegations as "unjust enrichment" claims. In *In re Cardizem I*, 105 F. Supp. 2d 618, 669 (E.D. Mich. 2000), the district court addressing a similar issue noted "courts often award equitable remedies under common law claims for unjust enrichment in circumstances where claims based upon contract or other state law violations prove unsuccessful." The court then proceeded to consider the sufficiency of the plaintiffs' state law unjust enrichment claims in light of the defendants' objections. *Id.* at 669-71. Here, both Plaintiffs have stated they are asserting their unjust enrichment claims as an alternative equitable remedy to their legal claims. This is exactly what the district court in *In re Cardizem I* allowed.

Defendants' last argument, however, does require additional attention. Defendants contend the Indirect Purchasers have not brought their unjust enrichment claims under any specific state laws. In *In re Cardizem I,* this was not an issue because the plaintiffs identified the state laws at issue in their complaints. *Id.* at 668. One reason a court might want the parties to include this information in the complaint is because the nature and/or the applicability of an unjust enrichment claim may differ depending upon the state. *See In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 419 n.3 (E.D. Pa. 2009). Moreover, as noted by Defendants, Plaintiffs' failure to identify the states at issue makes it difficult for Defendants to determine whether Plaintiffs have adequately stated a claim under a particular state's unjust enrichment law. Courts confronted with the issue now before this Court have responded in different ways. *See id.* at 419 (allowing the plaintiffs to amend their complaint so that it listed the state laws under which the claims were being brought); *see also Avenarius v. Eaton Corp.*, Civ. No. 11-09-SLR, 2012 WL 4903373, at *6-7 (D. Del. Oct. 16, 2012) (dismissing the plaintiffs' claims for not sufficiently identifying the relevant jurisdictions but also granting leave to amend the complaint); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 167 (E.D. Pa. 2009) (dismissing the plaintiffs' unjust enrichment claim for failing to connect their claim to the laws of a particular state). Here, the Indirect Purchasers have indicated in their brief and at oral argument that they believe Tennessee unjust enrichment laws should apply, and in the alternative the laws of California, Michigan, Mississippi, and New York should be applied. Although those state laws were not listed in the complaint, the Court concludes Defendants have been put on notice and Defendants have not been overly prejudiced by the omission. The Court will afford the Indirect Purchasers an opportunity to amend their complaint to include the state laws under which they are bringing their unjust enrichment claims.

D. Statute of Limitations

1. Federal Claims

Defendants argue Plaintiffs' federal claims are time-barred under the applicable four-year statute of limitations. The claims at issue are Claims I, II, and III of the Direct Purchasers' complaint and Claim I of the End Payors' complaint. Plaintiffs, on the other hand, argue their claims are not barred due to the "continuing violations" doctrine. Moreover, even if their claims did fall outside the applicable statute of limitations, they contend the statute of limitations can be tolled under the doctrine of fraudulent concealment.[19]

a. Continuing Violations Doctrine

Pursuant to 15 U.S.C. § 15b, actions brought under § 1 and § 2 of the Sherman Act must be "commenced within four years after the cause of action accrued." "Generally, a cause of action accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971). Moreover, "[f]or statute of limitations purposes, . . . the focus is on the timing of the causes of injury, i.e., the defendant's overt acts, as opposed to the effects of the overt acts." *DXS, Inc. v. Siemens Med. Sys., Inc.*, 100 F.3d 462, 467 (6th Cir. 1996) (quoting *Peck v. Gen. Motors Corp.*, 894 F.2d 844, 849 (6th Cir.1990) (per curiam)).

A court can determine there has been a "continuing antitrust violation," however, when "the plaintiff's interests are repeatedly invaded." *Id.* (citing *Peck*, 894 F.2d at 849). "When a continuing

[19] Neither Plaintiffs nor Defendants dispute that the statute of limitations is generally a matter that is raised as an affirmative defense. *See* Fed. R. Civ. P. 8(c). However, as noted by Defendants, "a defendant can satisfy its burden when the complaint's allegations, taken as true, 'show that relief is barred by the applicable statute of limitations'" (Court File No. 132 at 44 (citing *Jones v. Bock*, 549 U.S. 199, 215 (2007)).

antitrust violation is alleged, a cause of action accrues each time a plaintiff is injured by an act of the defendants." *Id.* (quoting *Barnosky Oils, Inc. v. Union Oil Co. of California*, 665 F.2d 74, 81 (6th Cir. 1981)). "[E]ven when a plaintiff alleges a continuing violation, an overt act by the defendant is required to restart the statute of limitations and the statute runs from the last overt act." *Id.* (quoting *Peck*, 894 F.2d at 849). The Sixth Circuit has determined an "overt act" for statute of limitations purposes must satisfy two requirements: "(1) it must 'be a new and independent act that is not merely a reaffirmation of a previous act'; and (2) it must 'inflict new and accumulating injury on the plaintiff.'" *Id.* (quoting *Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 238 (9th Cir. 1987)).

As noted by Defendants, the earliest complaint filed by any of the Plaintiffs was on January 13, 2012. Thus, under the applicable four-year statute of limitations, the cause of action would have needed to accrue no earlier than January 13, 2008. The majority of Plaintiffs' claims, however, pertain to conduct that occurred prior to this date. At best, according to Defendants, the only acts that continued into the relevant time period would be the '566 patent litigation, which Defendants contend caused Plaintiffs no injury, and the filing of various FDA citizen petitions, which Defendants contend are not at issue because the FDA law passed in September 2007 minimized the possibility of delay resulting from the filing of a citizen petition. The Court agrees with Defendants that most of the alleged anticompetitive conduct occurred prior to January 2008; hence, those acts would fall outside of the applicable statute of limitations. Moreover, it is unlikely that the few acts that occurred post-January 2008 would be sufficient to support Plaintiffs' § 1 and § 2 Sherman Act claims.

The Court, however, must also consider Plaintiffs' argument that the continuing violations

doctrine should be applied. Plaintiffs contend each sale of metaxalone that resulted in overcharges during the course of the conspiracy should be sufficient to restart the statute of limitations, and the overcharges in this case were a "continuing and accumulating harm" that lasted well into the limitations period. The Court observes that neither party offers a case from this circuit that directly addresses the continuing violations doctrine applied to a fact pattern similar to the one now before this Court. Nonetheless, there are several cases both from the Supreme Court and other circuits that are instructive for a variety of other reasons. For example, in *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481 (1968), a shoe manufacturer sued a lessor of shoe manufacturing machinery for monopolizing the industry in violation of § 2 of the Sherman Act. The plaintiff claimed the defendant's practice of leasing and refusing to sell certain major machines was part of its larger monopolization efforts and the plaintiff sought damages in the form of overcharges--that is, the difference between what it paid to lease the machinery during the relevant time period versus what it would have paid had the defendant been willing to sell the machinery. *Id.* at 483-84. The Supreme Court ultimately concluded that because the conduct at issue was a "continuing violation" that "inflicted continuing and accumulating harm" on the plaintiff, the plaintiff was not barred from bringing suit in 1955 even though he could have sued in 1912. *Id.* at 502 n.15. Thus, because the Supreme Court considered the defendant's conduct to be a continuing violation, each refusal to sell on the part of the defendant was treated as a new act for purposes of the statute of limitations.

Another case from which this Court gleans guidance is *Klehr v. A.O. Smith Corp.*, 521 U.S. 179 (1997). Although *Klehr* was a civil RICO case, the Supreme Court considered, *inter alia*, how the "continuing violation" doctrine was applied under antitrust law. In discussing the doctrine, the Court observed:

> Antitrust law provides that, in the case of a "continuing violation," say, a price–fixing conspiracy that brings about a series of unlawfully high priced sales over a period of years, "each overt act that is part of the violation and that injures the plaintiff," e.g., each sale to the plaintiff, "starts the statutory period running again, regardless of the plaintiff's knowledge of the alleged illegality at much earlier times." 2 Areeda ¶ 338b, at 145 (footnote omitted).

Id. at 189.[20]

In both instances above, the Supreme Court recognized that sales (or in the case of *Hanover Shoe*, a refusal to sell) resulting in overcharges could be taken into account when determining whether a continuing violation occurred. In particular, in *Klehr*, the Supreme Court discussed such sales in the context of a price-fixing conspiracy. While Defendants contend a price-fixing conspiracy is not directly analogous to the anticompetitive scheme or conspiracy alleged here, the Court finds the discussion in *Klehr* is still relevant to the instant case.

Though not binding on this Court, Plaintiffs have cited *Meijer, Inc. v. 3M*, CIV.A. 04-5871, 2005 WL 1660188 (E.D. Pa. July 13, 2005), as another case that supports its position regarding overcharges. In *Meijer*, the plaintiffs, direct purchasers of tape from the defendant 3M, sued the defendant for monopolization under § 2 of the Sherman Act. *Id.* at *2. The plaintiffs alleged the defendant maintained monopoly power by using bundled rebate programs and making exclusive dealing arrangements with certain retailers. *Id.* Defendant's conduct allegedly kept the prices for invisible and transparent tape at supracompetitive levels and caused the plaintiffs to incur overcharges dating back to 1993; the initial overt act of unlawfully maintaining monopoly power fell outside the applicable statute of limitations. *Id.* at *2-3. The court concluded the overcharges

[20] On the facts of the RICO case before it, where the plaintiffs alleged the defendants made misrepresentations about a defective product over time, the Supreme Court ultimately concluded the plaintiffs' claims were time-barred. *Id.* at 190.

incurred by the plaintiffs were sufficient to bring the defendants' anticompetitive conduct within the statute of limitations after taking into account the continuing violations doctrine. *Id.* at *4. Referencing the Areeda treatise, the court observed:

> While a leading commentator has noted that 'it should seem that high prices following . . . the creation of a monopoly are mere inertial consequences one naturally expects to flow from such acts,' Areeda ¶ 320 at 210, it has long been held that 'a purchaser suing a monopolist for overcharges paid within the previous four years may satisfy the conduct prerequisite to recovery by pointing to anticompetitive actions taken before the limitations period. *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 296 (2d Cir.1979).

Id. at *3.[21] The court also noted the United States Court of Appeals for the Third Circuit has distinguished between an "'overt act' necessary to show the existence of a [continuing violation], and, on the other hand, an injurious act causing damages within the limitations period." *Id.* (*quoting In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1172 (3d Cir.1993)). The district court further observed "courts have held that, in purchaser antitrust actions, the requisite injurious act within the limitations period can include being overcharged as the result of an unlawful act which took place outside the limitations period but continues to allow the defendant to maintain market control." *Id.* at *4 (citing *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 551 (D. N.J. 2004), and *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 365, 378 (S.D.N.Y. 2002)). Considering the facts before it and the relevant law, the court concluded the monopoly claim was not time-barred even though the initial overt act occurred outside the limitations period because that act "continues to allow 3M to commit the injurious act of overcharging Meijer and other purchasers." *Id.* at *4.

The court in *Meijer* is not alone in its conclusions regarding overcharges. *See In re K-Dur*

[21] The Areeda treatise, on the other hand, discounts the weight and authority of the *Berkey Photo* decision. 2 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 320c4 (2d. Ed. 2000).

Antitrust Litig., 338 F. Supp. 2d at 551 (concluding the plaintiffs' § 1 Sherman Act claims against the defendants--who allegedly entered into settlement agreements that had the effect of delaying the entry of a generic potassium chloride supplement in the market--were not time-barred to the extent the plaintiffs were overcharged for the brand name drug during the four-year limitations period); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d at 380 (concluding under the continuing violations doctrine that the purchaser plaintiffs' Sherman Act claims would survive the defendants' 12(b)(6) motion "to the extent the claims are based on allegations of injury arising from purchases of Buspar® at allegedly inflated prices beginning four years prior to the filings of their respective Complaints"); *see also In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1172 (3d Cir. 1993) (observing the plaintiffs had satisfied their burden of establishing a continuing violation when they showed an injurious act that continued into the limitations period, namely, artificially inflated dock handling rates).

Defendants cite a host of cases in support of their position the continuing violations doctrine should not be applied to the facts of the instant case. *See, e.g., Peck v. Gen. Motors Corp.*, 894 F.2d 844 (6th Cir. 1990); *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261 (7th Cir. 1984). However, as noted by Plaintiffs, some of these cases are distinguishable at the outset because the claims are brought by competitors in the relevant market (or other parties), not purchasers. *Cf. Molecular Diagnostics Labs. v. Hoffmann-La Roche Inc.*, 402 F. Supp. 2d 276, 286 (D.D.C. 2005) (determining the plaintiffs--who were purchasers, not competitors--could pursue their claims under the continuing violation theory because each time they were forced to pay an overcharge a new injury accrued). Defendants also cite *Kaiser Found. v. Abbott Labs.*, CV02-2443-JFWFMOX, 2009 WL 3877513 (C.D. Cal. Oct. 8, 2009) as being analogous to the instant case. In *Kaiser*, however,

the district court was considering a summary judgment motion on the plaintiff's remaining claim alleging the defendant had enforced a patent procured by fraud in violation of § 2 of the Sherman Act. *Id.* at *2. Among other things, the court determined the plaintiff's claim was time-barred because all of the anticompetitive acts at issue occurred prior to the start of the limitations period and, notably, even the sales made by the defendant at an artificially inflated price occurred prior to the limitations period. *Id.* at *6 ("any antitrust injury Plaintiff might have been suffering by paying an alleged monopoly price for Hytrin as a result of Defendant's alleged predatory conduct in keeping generic competition off the market had not only accrued but had ended by October 27, 1999," which would have been prior to the commencement of the applicable limitations period).[22]

[22] Though not the basis for its decision, the court also opined "the statute of limitations is not extended by continued sales at an allegedly monopolistic price because the 'monopolist's simple charging of its profit-maximizing price is a naturally expected consequence of a monopoly and can hardly be said to be [an] independent [act].'" *Id.* (citing II Areeda & Hovenkamp, *Antitrust Law*, ¶ 320c4, at 298-99 (3d ed. 2007)). The court, again citing the Areeda treatise, also noted that "if 'mere[ly] charging ... a monopoly price constitutes a 'continuing violation' tolling the statute, then we have indefinitely lengthened the statute of limitation." *Id.* (citing II Areeda & Hovenkamp, *Antitrust Law*, ¶ 320c, at 286 (3d ed. 2007)). *See DXS, Inc. v. Siemens Med. Sys., Inc.*, 100 F.3d 462, 467-68 (6th Cir. 1996) (observing that "[a]cts that simply reflect or implement a prior refusal to deal . . . or acts that are merely 'unabated inertial consequences' (of a single act) . . . do not restart the statute of limitations" (citations omitted)).

While this is one of Defendants' strongest arguments in favor of rejecting the notion that new sales of a product at an artificially inflated price by a monopolist should restart the limitations period, the Court observes that the instant case involves more than just the alleged monopolistic conduct of King. Here, the Court must also consider the broader anticompetitive scheme or conspiracy between King and Mutual as alleged by Plaintiffs. That conduct involved King and Mutual conspiring to delay the entry of a generic into the market and keeping the prices at an artificially inflated price. Presumably, taking into account both Defendants' overt acts to maintain the conspiracy--though most of those acts occurred outside of the limitations period--as well as the injurious acts that resulted in overcharges continuing into the limitations period, the Court could conclude Plaintiffs' claims adequately satisfy the continuing violations doctrine. Moreover, the Court observes Plaintiffs' damages would still be limited to the four year limitations period unless Plaintiffs are successful at proving fraudulent concealment, which would toll the statute of limitations.

Thus, notwithstanding the lack of case law from this circuit applying the continuing violations doctrine to facts similar to those in the instant case, the Court concludes Plaintiffs should be allowed to proceed with their claims because--even if most or all of the overt acts alleged as part of the continuing conspiracy occurred outside the limitations period--Plaintiffs have sufficiently alleged those acts resulted in Plaintiffs being overcharged for metaxalone well into the limitations period. With that said, the Court recognizes this is a complex issue and only reaches this conclusion after giving careful thought to how other courts faced with similar fact patterns have addressed this matter.[23]

Alternatively, even if the continuing violations doctrine is not applicable, Plaintiffs' claims would not be time-barred because they have also plausibly alleged facts to toll the statute of limitations under the fraudulent concealment doctrine, which will be discussed in the next subsection.

b. Fraudulent Concealment

Even if the Court had determined the continuing violations doctrine did not apply, the statute of limitations would be equitably tolled if Plaintiffs sufficiently alleged they could not uncover the alleged antitrust violations under the doctrine of "fraudulent concealment." To establish fraudulent concealment, the plaintiff must plead: "(1) wrongful concealment of their actions by the defendants; (2) failure of the plaintiff to discover the operative facts that are the basis of his cause of action within the limitations period; and (3) plaintiff's due diligence until discovery of the facts." *Carrier*

[23] The Court's decision, however, is also based in part upon the facts as they are alleged by the Plaintiffs. As the case develops and the facts are more fully fleshed out by the parties, the Court is willing to revisit the statute of limitations issue if it appears Plaintiffs' claims do, in fact, fall outside the applicable statute of limitations and the continuing violations doctrine does not apply.

Corp. v. Outokumpu Oyj, 673 F.3d 430, 446 (6th Cir. 2012) (quoting *Dayco Corp. v. Goodyear Tire & Rubber Co.*, 523 F.2d 389, 394 (6th Cir. 1975)). Fraudulent concealment claims must be pleaded with particularity. *See* Fed. R. Civ. P. 9(b); *Carrier Corp.*, 673 F.2d at 446 (citing *Friedman v. Estate of Presser*, 929 F.2d 1151, 1160 (6th Cir. 1991)).

When pleading "wrongful concealment" the plaintiff must allege "affirmative acts of concealment." *Hamilton Cnty. Bd. of Comm'rs v. Nat'l Football League*, 491 F.3d 310, 319 (6th Cir. 2007). Moreover, "mere silence or unwillingness to divulge wrongful activities is not sufficient." *Carrier Corp.*, 673 F.3d at 446 (quoting *Browning v. Levy*, 283 F.3d 761, 770 (6th Cir. 2002)). The court must instead consider whether there is a "trick or contrivance intended to exclude suspicion and prevent inquiry." *Id.* at 446-47 (quoting *Pinney Dock & Transp. Co. v. Penn Cent. Corp.*, 838 F.2d 1445, 1467 (6th Cir. 1988)). With respect to the due diligence prong, "the court should evaluate such acts of active concealment as a factor in determining whether the plaintiff's investigation was reasonable under the circumstances." *Id.* (citing *Campbell v. Upjohn Co.*, 676 F.2d 1122, 1128 (6th Cir. 1982)). "[A]ctions such as would deceive a reasonably diligent plaintiff will toll the statute; but those plaintiffs who delay unreasonably in investigating circumstances that should put them on notice will be foreclosed from filing, once the statute has run." *Id.*

Defendants argue Plaintiffs cannot satisfy the three-prong test stated above because, first, there was no "concealment" on the part of Defendants. Defendants contend all of their acts were a matter of public record. Moreover, they claim there was nothing "wrongful" about their conduct. Finally, Defendants claim that given the public nature of their acts there was no reason Plaintiffs could not have discovered the facts of this case at an earlier date.

Although Plaintiffs are subject to a higher pleading standard, they have nonetheless plausibly

alleged for purposes of this motion that the doctrine of fraudulent concealment applies. With respect to wrongful concealment, Plaintiffs allege a number of acts on the part of Defendants that together satisfy this prong. First, Plaintiffs allege executives from King and Mutual participated in a secret meeting in October 2005 (DPP Compl. ¶ 175; EPP Compl. ¶ 169). At the meeting, a King executive indicated that King would "make substantial annual payments" to certain generic manufacturers in order to settle patent litigation cases threatening King's monopoly. Within two months of the meeting, King and Mutual had entered into the agreement at issue and the two companies then proceeded to engage in acts to hide the conspiracy (DPP Compl. ¶¶ 171-253; EPP Compl. ¶¶ 165-247). Those acts included staying the '102 patent litigation even though there was no longer a justiciable dispute due to the conspiracy. They also include Defendants' efforts to file FDA citizen petitions, many of which would have been contrary to Mutual's interests prior to its decision to enter the conspiracy. Plaintiffs even observe Mutual still maintained that it was pursuing its ANDA application when it filed the citizen petitions (*see* DPP Compl. ¶¶ 184, 210, 232; EPP Compl. ¶¶ 178, 204, 226).

Defendants argue none of the aforementioned acts were "concealed" nor were they "wrongful" because they were all public acts. Defendants compare the facts of this case to those in *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 221-27 (E.D.N.Y. 2003), in which the district court concluded the plaintiffs had failed to adequately allege fraudulent concealment. In *In re Ciprofloxacin*, the plaintiffs alleged, *inter alia*, that the defendants had met secretly and agreed to suppress competition from generic manufacturers. *Id.* at 222. The plaintiffs also alleged the defendants took affirmative steps such as agreeing to keep the terms of their unlawful agreements secret. *Id.* The problem noted by the court, however, was that the defendants

affirmatively disclosed information pertaining to the agreements to the public, including but not limited to putting out press releases related to the settlement agreement and its principal terms as well as filing information about the documents in public records. *Id.* at 223. The court also noted that allegations of "'secret meetings' that led to an allegedly unlawful stipulation and, we can infer, the challenged agreements" without more could not satisfy the pleading requirements of Rule 9(b). *Id.* at 227.

Here, while most of the events were part of the public record--including but not limited to a redacted copy of the agreement and press release; the patent litigation cases; the citizen petitions; and the patents and Orange Book listings--some of these acts were not entirely public. For instance, Plaintiffs contend they did not learn of the October 2005 meeting until the SigmaPharm complaint was filed in 2010 (DPP Compl. ¶¶ 296-99; EPP Compl. ¶¶ 297-300). Yet Plaintiffs allege this meeting played a significant role in getting the conspiracy underway and they have alleged details about the meeting--for example, the who, what, when, and where--that were not as apparent in the complaint at issue in *Ciprofloxacin* (*see* DPP Compl. ¶ 175; EPP Compl. ¶ 169). Moreover, with respect to the written agreement, while Plaintiffs agree it was rather innocuous on its face, they contend the parts that were redacted are quite telling because Mutual ultimately received more than $200 million for its part in signing the agreement (*see* DPP Compl. ¶¶ 178-80; EPP Compl. ¶¶ 172-74).

Finally, all of this directly ties in with the issue of whether Plaintiffs adequately pleaded "due diligence." Defendants claim that because of the public nature of their acts, their acts should have excited suspicion and Plaintiffs' failure to investigate at the time those events took place shows they did not exercise due diligence. As an illustration, Defendants note that in *Dayco*, the Sixth Circuit

determined the plaintiff did not exercise due diligence when it failed to act despite Congressional hearings and an FTC suit exploring similar types of violations allegedly committed by the defendants. 523 F.2d 389, 394 (6th Cir. 1975). However, here, there was not a hearing or lawsuit comparable to those in *Dayco* and Plaintiffs allege they were not put on notice of the alleged conspiracy until the SigmaPharm complaint was filed in 2010 (DPP Compl. ¶¶ 296-99; EPP Compl. ¶¶ 297-300). It was through the SigmaPharm case that Plaintiffs learned of the secret meeting in 2005 and the nature of the payments from King to Mutual. Plaintiffs also contend that because Defendants made several efforts as noted above to conceal the nature of the conspiracy, none of their public acts would have excited suspicion.

Taking all of this into account, the Court believes Plaintiffs have adequately pleaded their fraudulent concealment claims. To the extent Defendants are challenging the substance of Plaintiffs' allegations--including but not limited to the issue of whether Plaintiffs could have or should have acted sooner--those challenges pertain to issues of fact that can be addressed at a later stage of litigation after the parties have engaged in discovery. Accordingly, the Court will not dismiss Plaintiffs' fraudulent concealment claims.

2. State Claims

Defendants seek dismissal of the majority of Plaintiffs' state law claims on the grounds that they are time-barred. Defendants argue the following claims must be dismissed: Claims I through VI of the Indirect Purchaser's complaint and Claims II through V of the End Payors' complaint. These claims allege violations of antitrust and consumer protection statutes for various states. The only state laws for which Defendants do not seek dismissal are Plaintiffs' antitrust claims brought under Tennessee and Wisconsin law, and the consumer protection statute claims brought under

Pennsylvania, Rhode Island, and Minnesota law (Court File No. 132 at 56-57 n.26).

The states at issue in this case either apply the "date of injury" rule or the "discovery" rule to determine when the statute of limitations begins to run. Among those that apply the "date of injury" rule,[24] the parties do not dispute that the state laws, though not identical, operate in a manner similar to the rules for federal antitrust law. In particular, the parties contend their arguments pertaining to the federal statute of limitations and the fraudulent concealment doctrine also apply to the state laws. The state antitrust statutes of limitations are four years and the state consumer protection statutes of limitations range in length from three to five years. Taking this into account, the alleged causes of action would have needed to accrue no earlier than January 13, 2008 for the antitrust claims and January 13, 2007 for some of the consumer protection statute claims. Very few, if any, of Plaintiffs' alleged anticompetitive acts would have occurred within these time periods and/or would have been sufficient to support Plaintiffs' claims if viewed separately. With that said, even if Plaintiffs' state law claims fell outside of the applicable statutes of limitations, Plaintiffs have adequately pleaded plausible facts as noted earlier that would satisfy the continuing violations doctrine and/or the fraudulent concealment doctrine.[25] Accordingly, the Court will not dismiss

[24] The state laws at issue include the antitrust laws of California, Florida, Michigan, Minnesota, Nebraska, New York, and North Carolina, and the consumer protection statutes of Arkansas, California, Nebraska, and New York. Defendants argue Arizona and Kansas also apply the "date of injury" rule, whereas Plaintiffs argue they apply the "discovery" rule. Because the Court concludes under either rule at this stage the claims will not be dismissed, the Court need not resolve the dispute over the appropriate rule to apply at this time.

[25] Although the Indirect Purchasers were not included in the Court's previous discussion of the continuing violation and fraudulent concealment doctrines, the Court acknowledges that the Indirect Purchasers' factual allegations are nearly identical to the Direct Purchasers and End Payors. Accordingly, the Court's determinations regarding whether Plaintiffs adequately alleged facts to support a continuing violation or the fraudulent concealment doctrine will also apply to the Indirect Purchasers at this stage.

Plaintiffs' state law claims that are governed by the "date of injury" rule. As the case progresses and discovery has been conducted, the Court is willing to revisit this issue in the event it becomes apparent Plaintiffs cannot demonstrate a particular state claim falls within the applicable statute of limitations and cannot establish either the continuing violation or fraudulent concealment doctrine applies.

With respect to the states that utilize the "date of discovery" rule,[26] the parties agree the general focus is on when the plaintiffs discovered or with reasonable diligence should have discovered their injury. Because Plaintiffs have adequately alleged facts at this stage to satisfy the federal fraudulent concealment standard, which though not identical would likely impose a higher standard than a state's discovery rule,[27] the Court concludes Plaintiffs should be allowed to proceed on these claims as well. In particular, Plaintiffs allege they did not discover the alleged antitrust violations until 2010 when the SigmaPharm complaint made Plaintiffs aware of information about King and Mutual's anticompetitive scheme that had previously been unavailable to the public. Plaintiffs also allege even with due diligence they would not have learned of Defendants' unlawful conduct prior to 2010 because Defendants' acts were self-concealing and would not have excited suspicion.

In sum, the Court will not dismiss Plaintiffs' state law claims as being time-barred at this stage.

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[26] The laws at issue include the state antitrust laws of Massachusetts, Mississippi, Nevada, New Mexico, and West Virginia, and the consumer protection statutes of Massachusetts, Missouri, and Virginia.

[27] The parties also again rely on their prior arguments under federal law with respect to the doctrine of fraudulent concealment in arguing why the discovery rule should or should not apply.

VI. CONCLUSION

For the foregoing reasons, the Court will **DENY** Defendants' motion to dismiss (Court File No. 84). Also, the Indirect Purchaser Plaintiffs will be allowed to amend their complaint to expressly name the state laws under which they bring their unjust enrichment claims.

An Order shall enter.

/s/
CURTIS L. COLLIER
UNITED STATES DISTRICT JUDGE